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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2101-2150

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

OSCAR R. EWING, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., December 22, 1947.

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DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2101. Adulteration and misbranding of dextrose injection and adulteration of epinephrine hydrochloride. U. S. v. Alpinol Corporation, Louis Rubella, and Ugo Quarantelli. Pleas of guilty. Fine of \$1,500 against the defendants, jointly. (F. D. C. No. 20153. Sample Nos. 4382-H, 5151-H.)

INFORMATION FILED: July 22, 1946, Southern District of New York, against The Alpinol Corporation, New York, N. Y., and Louis Rubella, president, and Ugo Quarantelli, secretary-treasurer, of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of September 26 and October 2, 1945, from the State of New York into the State of Pennsylvania.

LABEL, IN PART: "Dextrose Injection * * * Distributed by Physicians' Drug & Supply Co., Phila., Pa." or "Epinephrine Hydrochloride 1:1000."

NATURE OF CHARGE: Adulteration, Section 501 (b), both products purported to be and were represented as drugs, the names of which are recognized in the United States Pharmacopoeia, but their quality and purity fell below the official standard in the following respects, and their variations from the standard were not stated on the labels: The *dextrose injection* was not sterile but was contaminated with viable bacteria, yeast, and mold, and it contained undissolved material. The *epinephrine hydrochloride* had a lower potency than the official product, and it contained undissolved material.

* For failure to comply with the packaging requirements of an official compendium, see No. 2115; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2150; inconspicuousness, or absence, or failure to provide required label information, Nos. 2115, 2135; cosmetics, subject to the drug provisions of the Act, Nos. 2121, 2150.

Misbranding, Section 502 (j) the *dextrose injection* was dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling, "Note: The contents are for use at one time * * * Directions: Administer slowly intravenously."

DISPOSITION: September 6, 1946. Pleas of guilty having been entered, the court imposed a fine of \$500 against the defendants, jointly, on each of the 3 counts of the information.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2102. Misbranding of Pronto-Lax, Mineral Crystals, Famous Residuum, Nose Spraying Solution, and Eye Bath. U. S. v. Famous Mineral Water Co. and Howard Nevils. Pleas of guilty. Fine of \$100 against each defendant on count 1; fine of \$500 generally, but suspended for 3 years, against the defendants on the other counts of the information. (F. D. C. No. 20169. Sample Nos. 21861-H to 21865-H, incl.)

INFORMATION FILED: September 18, 1946, Northern District of Texas, against the Famous Mineral Water Co., a corporation, Mineral Wells, Tex., and Howard Nevils, secretary and treasurer of the corporation.

ALLEGED SHIPMENT: From the State of Texas into the State of Tennessee. The products were shipped on or about January 14 and April 3, 1945, and a number of circulars entitled "Dismuke's Famous Mineral Water" and "The Original and Genuine Famous Mineral Crystals" were shipped during December 1944.

PRODUCT: Analyses disclosed that the *Pronto-Lax* was an alkaline mineral water containing chiefly sodium sulfate (Glauber's salt) and sodium chloride (common table salt); that the *Mineral Crystals* was a partially crystallized sodium sulfate containing small amounts of sodium chloride and sodium carbonate; that the *Famous Residuum* was a concentrated mineral water containing mainly sodium chloride, sulfate, and carbonate, with some sodium nitrite; that the *Nose Spraying Solution* was a mineral water containing mainly sodium chloride, sulfate, and carbonate, with some sodium nitrate; and that the *Eye Bath* was essentially of the same composition as the *Nose Spraying Solution*.

LABEL, IN PART: "Dismuke's Pronto-Lax Concentrated Famous Mineral Well Water," "Dismuke's Famous Mineral Crystals," "Famous Residuum Made From The Crystals of the Famous Mineral Well Water," "Dismuke's Nose Spraying Solution," or "Dismuke's Eye Bath."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the respective products were false and misleading since the articles would not be effective to accomplish the purposes represented and suggested. The following false and misleading representations were made for the articles in the labeling:

That the *Pronto-Lax* was a tonic; that it would eliminate toxic poisons from the system, which poisons cause the majority of human ailments, and would eliminate poisons in a natural manner; that it would be beneficial to the stomach, kidneys, and liver; that it was life-saving, and would help suffering humanity; that it would make the user a "new man," and would keep the user in good health; and that it would improve digestion, and would be efficacious in the cure, mitigation, treatment, and prevention of diabetes, enlarged liver, carbuncle, mucous colitis, stomach trouble, ulcerated stomach, colon trouble, sciatica, rheumatism, hives, and autointoxication.

That the *Mineral Crystals* would be efficacious in the cure, mitigation, treatment, and prevention of acid stomach, colds, headaches, biliousness, indigestion, bad complexion, rheumatism, arthritis, neuritis, high blood pressure, and diabetes; that it would purify the system; that it would be beneficial after excessive eating and drinking; that it would enable the user to get well; and that it would eliminate toxic poison in the system.

That the *Famous Residuum* possessed tonic and healing properties, and would be efficacious in the cure, mitigation, treatment, and prevention of cuts, burns, insect bites, eczema, rash, poison ivy, acid stomach, acute indigestion, stomach trouble, ulcerated stomach, colic, and similar troubles; that it would enable the user to breathe normally and sleep soundly; and that it would tone up the digestive tract and prolong life.

That the *Nose Spraying Solution* would be efficacious in the cure, mitigation, treatment, and prevention of head colds, hay fever, sinus, and catarrhal trouble.

That the *Eye Bath* possessed healing properties, and was an antiseptic; and that it would be efficacious in the cure, mitigation, treatment, and prevention of eye strain, blue, granulated lids, and sore eyes.

Further misbranding, Section 502 (a), the labeling of the *Pronto-Lax* was false and misleading since it represented and suggested that the article contained healing minerals, and that it was recommended by the Food and Drug Administration as the greatest mineral water in the world. The article did not contain healing minerals, and was not recommended by the Food and Drug Administration.

Misbranding Section 502 (f) (2), the *Pronto-Lax* and *Mineral Crystals* were laxatives; and their labeling failed to warn that they should not be used in the presence of abdominal pain, nausea, vomiting, or other symptoms of appendicitis, and that frequent or continued use of the articles might result in dependence upon laxatives to move the bowels.

DISPOSITION: November 12, 1946. Pleas of guilty having been entered, the court imposed a fine of \$100 against each individual on count 1 of the information, which related to the *Pronto-Lax*. The court imposed also a fine of \$500, generally, upon the defendants on the other counts, but suspended the latter fine for 3 years.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2103. Adulteration of amphetamine sulfate tablets. U. S. v. 576 Bottles and 1 Drum * * *. (F. D. C. No. 22375. Sample No. 52302-H.)

LIBEL FILED: January 17, 1947, District of Minnesota.

ALLEGED SHIPMENT: On or about August 31, 1946, by the Penn Lee Products, from St. Paul, Minn.

PRODUCT: 576 1,000-tablet bottles of *amphetamine sulfate tablets* and 1 unlabeled drum containing broken tablets of the same article removed from the labeled bottles, at St. Paul, Minn.

LABEL, IN PART: (Bottles) "Amphetamine Sulfate Tablets."

NATURE OF CHARGE: Adulteration, Section 501 (a) (2), desoxyephedrine hydrochloride had been substituted for amphetamine sulfate in the article.

DISPOSITION: March 27, 1947. No claimant having appeared, judgment was entered ordering the product destroyed.

2104. Adulteration of poke root and skullcap herb. U. S. v. 21 Bags, etc. (F. D. C. No. 19422. Sample Nos. 8617-H, 8618-H.)

LIBEL FILED: March 14, 1946, District of New Jersey.

ALLEGED SHIPMENT: On or about January 30, 1946, by the St. Louis Commission Co., from St. Louis, Mo.

PRODUCT: 21 bags containing approximately 1,535 pounds of *poke root* and 3 bales containing approximately 746 pounds of *skullcap herb* at Jersey City, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the articles consisted in whole or in part of filthy substances by reason of the presence of rodent hair fragments, insects, and insect fragments.

DISPOSITION: April 29, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2105. Alleged adulteration and misbranding of Hormo-Fen Capsules and alleged misbranding of Hormo-Gen Capsules. U. S. v. Harlow B. Boyle and Charles E. Boyle (Boyle & Co.). Pleas of not guilty. Tried to the court. Verdict of not guilty. (F. D. C. No. 20190. Sample Nos. 28653-H, 32251-H.)

INFORMATION FILED: October 15, 1946, Southern District of California, against Harlow B. Boyle and Charles E. Boyle, partners, trading as Boyle & Co., Los Angeles, Calif.

*See also No. 2101.

ALLEGED SHIPMENT: On or about April 28 and August 9, 1945, from the State of California into the States of Washington and Arizona.

LABEL, IN PART: "Hormo-Fen (Female Hormone) 2,000 International Units Per Capsule," or "Hormo-Gen (Male Hormone) 10 Capon Units Per Capsule."

NATURE OF CHARGE: *Hormo-Fen.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, since each capsule of the article was represented to contain 2,000 International Units of estrogenic substance, whereas each capsule contained less than 2,000 International Units of estrogenic substance. Misbranding, Section 502 (a), the label statement, "Each capsule contains 2,000 International Units of Estrogenic Substance," was false and misleading. Further misbranding, Section 502 (e), the article was not designated solely by a name recognized in an official compendium, it was fabricated from 2 or more ingredients, and its label failed to bear the common or usual name of each active ingredient. The label designation "Estrogenic Substance" is not the common or usual name of any particular active ingredient, but is a generic name for a class of substances.

Hormo-Gen. Misbranding, Section 502 (a), the label statement, "Hormo-Gen (Male Hormone) * * * To support androgenic parenteral or inunction therapy in hypogonadism in the male and the male climacteric," was false and misleading in that the article would not be efficacious for such purposes.

The information contained also charges of adulteration and misbranding of Nova-Tron Capsules, Mina-Vita Tablets, and Vita-Health Tablets under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: February 18, 1947, the defendants having entered pleas of not guilty, the case came on for trial before the court. After consideration of the evidence and arguments of counsel, the court returned a verdict of not guilty, and the information was ordered dismissed.

2106. Adulteration and misbranding of vitamin B complex and misbranding of Ovhormone. U. S. v. The Alpinol Corporation, Louis Rubella, and Ugo Quarantelli. Pleas of guilty. Fine of \$2,000 against the defendants, jointly. (F. D. C. No. 17827. Sample Nos. 4457-H, 4460-H, 16551-H.)

INFORMATION FILED: July 22, 1946, Southern District of New York, against the Alpinol Corporation, New York, N. Y., and Louis Rubella, president, and Ugo Quarantelli, secretary-treasurer, of the corporation.

ALLEGED SHIPMENT: On or about March 27 and April 17 and 30, 1945, from the State of New York into the States of Pennsylvania and Illinois.

PRODUCT: The product labeled "Vitamin B Complex" was devoid of thiamine and riboflavin, two of the vitamin constituents declared on the label. It had the characteristics of an oil, being immiscible with water. Substances immiscible with water may cause serious consequences if injected intravenously. The product was apparently a hormone in oil solution, to which had been applied the label of a different product.

LABEL, IN PART: "Vitamin B Complex No. 2 * * * Intramuscular Intravenous * * * Distributed by D. F. Strohm Upper Darby, Pa.;" "Ovhormone 10,000 I. U. * * * Distributed by Edgar Metz Lansdowne, Pa.," or "Ovhormone 30,000 I. U. * * * Distributed By The National Colloid Co. Chicago, Ill."

NATURE OF CHARGE: *Vitamin B Complex.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess. It was represented to contain in each cubic centimeter 20 milligrams of thiamine hydrochloride and 1 milligram of riboflavin, whereas it contained no thiamine hydrochloride or riboflavin. Misbranding, Section 502 (a), the labeling of the article was misleading in that the label statement "Intravenous" represented and suggested that the article was for intravenous use, and the labeling failed to reveal the material fact with respect to the consequences which may result from the use of the article under the conditions of use prescribed in its labeling, i. e., intravenously.

Ovhormone. Misbranding, Section 502 (a), the label statement, "Contains * * * Estrogenic Hormone derived from gravid mare's urine," was false and misleading since it represented and suggested that the estrogenic substance present in the article was estrogenic substance as it occurs in and is extracted from gravid mare's urine, whereas the estrogenic substance present

was not estrogenic substance as it occurs in and is extracted from gravid mare's urine.

DISPOSITION: September 6, 1946. Pleas of guilty having been entered, the court imposed a fine of \$500 against the defendants jointly, on each of the 4 counts of the information.

2107. Adulteration and misbranding of sodium morrhuate and misbranding of estrogenic substance. U. S. v. Estro Chemical Co., Inc., Joachim Anschel, and Morton G. Falk. Pleas of guilty. Estro Chemical Co., Inc., fined \$1,000; Joachim Anschel, \$500; and Morton G. Falk, \$750. (F. D. C. No. 16596. Sample Nos. 54693-F, 87020-F, 4071-H.)

INFORMATION FILED: March 27, 1947, Southern District of New York, against the Estro Chemical Co., Inc., New York, N. Y., Joachim Anschel, and Morton G. Falk.

ALLEGED SHIPMENT: On or about October 2 and November 27, 1944, and February 8, 1945, from the State of New York into the States of Illinois, Michigan, and Pennsylvania.

LABEL, IN PART: "Sodium Morrhuate 5%," or "Estrogenic Substance."

NATURE OF CHARGE: *Sodium morrhuate.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since it purported and was represented to contain 5 percent of sodium morrhuate, but contained a small amount. Misbranding, Section 502 (a), the statement "Sodium Morrhuate 5%" borne on the label was false and misleading.

Estrogenic substance. Misbranding, Section 502 (a), the statement "Containing Estrone and Estradiol derived from natural sources" on the label of one lot, and the statement "This is a mixture of natural estrogens containing estrone and estradiol" on the label of the other lot were false and misleading since the article did not contain any estrone.

DISPOSITION: April 3, 1947. Pleas of guilty having been entered, the corporation was fined \$1,000; Joachim Anschel, \$500; and Morton G. Falk, \$750.

2108. Adulteration and misbranding of rubbing compound and mouth wash. U. S. v. Lloyd Johnson (Lura-Glo Laboratories). Defendant's motion to dismiss denied. Plea of nolo contendere. Fine, \$1,100. (F. D. C. No. 17876. Sample Nos. 25549-H, 27251-H, 27822-H, 36220-H.)

INFORMATION FILED: June 11, 1946, Southern District of California, against Lloyd Johnson, trading as the Lura-Glo Laboratories, Oakland, Calif.

ALLEGED SHIPMENT: Between the approximate dates of January 2, 1945, and July 8, 1945, from the State of California into the States of Utah, Washington, Oregon, and Idaho.

LABEL, IN PART: "LG Rubbing Compound Isopropyl Alcohol 70% by Volume," or "LG Antiseptic Mouth Wash An excellent aid for the relief of sore throat, sore mouth * * * sore gums."

NATURE OF CHARGE: *Rubbing Compound.* Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess in that it was represented to contain 70 percent by volume of isopropyl alcohol, but contained a smaller amount. Misbranding, Section 502 (a), the label statement, "Isopropyl Alcohol 70% by Volume," was false and misleading.

Antiseptic Mouth Wash. Adulteration, Section 501 (c), its strength differed from and its quality fell below that which it was represented to possess. The article was represented to be an antiseptic, but was not an antiseptic within the meaning of Section 201 (c), since it was not a germicide when used in the dilution recommended in the labeling; and it did not purport to be and was not represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body. Misbranding, Section 502 (a), the label statement, "Antiseptic," was false and misleading; the label statement, "Contains * * * 5% Alcohol," was false and misleading since the article contained more than 5 percent of alcohol; and the label statement, "Aid for the relief of sore throat, sore mouth * * * sore gums," was false and misleading since the article would not be an effective treatment for sore throat, sore mouth, and sore gums.

DISPOSITION: October 15, 1946. The defendant's motion to dismiss having been denied, a plea of nolo contendere was entered and the court imposed a fine of \$1,100.

2109. Adulteration of saccharin tablets. U. S. v. 174 Cards * * *. (F. D. C. No. 22244. Sample No. 72941-H.)

LIBEL FILED: February 4, 1947, District of Kentucky.

ALLEGED SHIPMENT: On or about January 4, 1947, by the National Specialty Company, from Nashville, Tenn.

PRODUCT: 174 cards, each containing 12 envelopes, of *saccharin tablets* at Louisville, Ky. Analysis showed that the product contained an average of 114 percent of the labeled amount of soluble saccharin per tablet, and that the average number of tablets in an envelope was 31.

LABEL, IN PART: (Cards) "Nasco Brand Saccharin Tablets 35's One Quarter Grain"; (envelopes) "Nasco Brand Saccharin Tablets $\frac{1}{4}$ Grain Soluble."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, "Saccharin Sodium Tablets [Soluble Saccharin Tablets]," the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth in the compendium since the article contained more than 110 percent of the declared amount of soluble saccharin.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: March 14, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2110. Adulteration and misbranding of saccharin tablets. U. S. v. 21 Cartons * * *. (F. D. C. No. 22322. Sample No. 39846-H.)

LIBEL FILED: February 28, 1947, Eastern District of Illinois.

ALLEGED SHIPMENT: On or about January 3, 1947, by the National Specialty Co., from Nashville, Tenn.

PRODUCT: 21 cartons, each containing 12 100-tablet bottles, of *saccharin tablets* at Carbondale, Ill. Analysis showed that the tablets labeled $\frac{1}{4}$ grain contained an average of 131 percent of the labeled amount, and that the tablets labeled $\frac{1}{2}$ grain contained an average of 69 percent of the labeled amount, of soluble saccharin. The United States Pharmacopoeia provides that saccharin tablets shall contain not less than 95 percent and not more than 110 percent of the labeled amount of soluble saccharin.

LABEL, IN PART: "Nasco Brand 100 Saccharin Tablets Soluble $\frac{1}{4}$ [or " $\frac{1}{2}$ "] grain equal 1 lump [or "2 lumps"] sugar."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, "Saccharin Sodium Tablets [Soluble Saccharin Tablets]," the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth in such compendium.

Misbranding, Section 502 (a), the label statements, "Saccharin Tablets $\frac{1}{4}$ [or " $\frac{1}{2}$ "] grain equals 1 lump [or "2 lumps"] sugar * * * Each Tablet is equal in sweetening power to 1 lump [or "2 lumps"] or 1 teaspoonful [or "2 teaspoonsfuls"] of sugar," were false and misleading as applied to an article containing in the smaller size more than $\frac{1}{4}$ grain, and in the larger size less than $\frac{1}{2}$ grain, of soluble saccharin.

DISPOSITION: March 18, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2111. Adulteration and misbranding of hydrogen peroxide. U. S. v. 10 Cases * * *. (F. D. C. No. 21882. Sample No. 67421-H.)

LIBEL FILED: December 23, 1946, Northern District of Oklahoma.

ALLEGED SHIPMENT: On or about June 10, 1946, by the Loveless Pharmacal Co., from Springfield, Mo.

PRODUCT: 10 cases, each containing 24 8-ounce bottles, of solution of *hydrogen peroxide* at Tulsa, Okla. The product contained less than $\frac{1}{5}$ the amount of H₂O₂ (hydrogen peroxide) required by the United States Pharmacopoeia, and it would yield not more than $\frac{1}{6}$ the volume of oxygen indicated on the label. It contained no acetanilid.

LABEL, IN PART: "Hydrogen Peroxide 10 Volumes 3% $\frac{3}{16}$ Gr. Acetanilid to oz. * * * Active Ingredients H₂O₂ 3%."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, "Solution of Hydrogen Peroxide," the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth in that compendium.

Misbranding, Section 502 (a), the label statements, "Hydrogen Peroxide 10 Volumes 3% 3/16 Gr. Acetanilid to oz. * * * Active Ingredients H₂O₂ 3%," were false and misleading.

DISPOSITION: January 13, 1947. The shipper having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

2112. Adulteration of thiamine hydrochloride. U. S. v. 28 Vials * * *. (F. D. C. No. 22188. Sample No. 90725-H.)

LIBEL FILED: January 15, 1947, District of Columbia.

ALLEGED SHIPMENT: On or about June 7 and September 30, 1946, by the Gotham Pharmaceutical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 28 30-cc. vials of *thiamine hydrochloride* at Washington, D. C.

LABEL, IN PART: "Thiamine Hydrochloride 100 mgm. * * * For Intramuscular or Intravenous Use."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, since it contained undissolved material. An article intended for intravenous use should be free from undissolved material.

DISPOSITION: April 18, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2113. Adulteration of strontium bromide. U. S. v. 61 Vials * * *. (F. D. C. No. 22195. Sample Nos. 64513-H, 76006-H.)

LIBEL FILED: January 23, 1947, District of New Jersey.

ALLEGED SHIPMENT: On or about August 31, 1946, by Vincent Christina & Co., Inc., from New York, N. Y.

PRODUCT: 61 10-cc. vials of *strontium bromide* at Jersey City, N. J.

LABEL, IN PART: "Strontium Bromide N. F. Crystals 1 Gm. For Intravenous Use."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, since it contained undissolved material. An article which is represented to be for intravenous use should be free from undissolved material.

DISPOSITION: February 24, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2114. Adulteration and misbranding of Densanto Caps. U. S. v. 56 Bottles * * *. (F. D. C. No. 21995. Sample No. 72752-H.)

LIBEL FILED: December 27, 1946, District of Colorado.

ALLEGED SHIPMENT: On or about January 4, 1946, by Barlow, Wright & Shores, Inc., from Cedar Rapids, Iowa.

PRODUCT: 56 100-capsule bottles of *Densanto Caps* at Denver, Colo. Analysis of a sample of the product showed that the capsules consisted essentially of santonin, 3 grains; calomel, 2.59 grains; aloin; sodium bicarbonate; and thymol.

LABEL, IN PART: "Densanto Caps * * * 3 Grain Capsules * * * Each Capsule Contains * * * Calomel U. S. P. 3 Grains."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, since each capsule did not contain 3 grains of calomel.

Misbranding, Section 502 (a), the label statement "Each Capsule Contains * * * Calomel U. S. P. 3 grains" was false and misleading; and, Section 502 (a), the label statement "For the Removal of Large Round Worms in Swine" was false and misleading since the article when used as directed would not be effective in the removal of large round worms in swine.

DISPOSITION: February 17, 1946. The shipper having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

2115. Adulteration and misbranding of adhesive strips. U. S. v. Gero Products, Inc., and Gregory S. Roisen. Pleas of guilty. Fine of \$50 against each defendant. (F. D. C. No. 20170. Sample Nos. 6815-H, 6816-H.)

INFORMATION FILED: December 4, 1946, District of Massachusetts, against Gero Products, Inc., South Boston, Mass., and Gregory S. Roisen, president of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of December 12, 1944, and February 15, 1945, from the State of Massachusetts into the State of New York.

LABEL, IN PART: "Home-aid Adhesive Strips"; [In small inconspicuous type on back of carton] "These Strips have not been Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), (1 shipment) the article purported to be a drug, "Adhesive Absorbent Gauze [Adhesive Absorbent Compress]," the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality fell below the official standard, since the standard provides that "Adhesive Absorbent Gauze" is prepared by affixing an absorbent compress to a strip of adhesive plaster, and that the weight of the compress is not less than that of a compress of the same area composed of four layers of Type I absorbent gauze, whereas the weight of the compress with which the article was prepared was less than that prescribed by the standard; and its difference in strength and quality from the standard was not plainly stated on its label.

Misbranding, Section 502 (c), (both shipments) the information required by law to appear on the label was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, and devices in the labeling) as to render it likely to be read by the ordinary individual under customary conditions of purchase and use, in that its quality and purity fell below the official standard for adhesive absorbent compress since the article was not a sterile individual dressing, as required by the standard, but was unsterile; and the statement of its difference in quality and purity from the standard was not prominently placed on the label, but was printed in small, partly illegible type on the back of the package containing the article.

Further misbranding, Section 502 (g), the article was not packaged as prescribed in the United States Pharmacopoeia, since it was not packaged individually in such manner that sterility would be maintained until the individual package was opened, and one or more individual packages were not packed in a second protective container.

DISPOSITION: February 18, 1947. Pleas of guilty having been entered, the court imposed a fine of \$50 against each defendant.

2116. Adulteration of adhesive tape. U. S. v. 39 Cartons * * *. (F. D. C. No. 17474. Sample Nos. 16282-H, 16283-H.)

LIBEL FILED: September 24, 1945, Northern District of Illinois.

ALLEGED SHIPMENT: On or about June 20, 1945, by the Gotham Aseptic Laboratory Co., Inc., from New York, N. Y.

PRODUCT: 29 cartons, each containing 12 5-yard rolls, of *adhesive tape* at Chicago, Ill.

LABEL, IN PART: "Stickrite [or "Waterproof"] Adhesive Tape Gotham."

NATURE OF CHARGE: Adulteration, Section 501 (b), the strength of the article differed from, and its quality fell below, the standard as set forth in the United States Pharmacopoeia, since its adhesive strength when determined by the method specified in that compendium was less than the required strength of 40 pounds.

DISPOSITION: October 7, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2117. Adulteration and misbranding of prophylactics. U. S. v. 30 Gross * * * (and 1 other seizure action). (F. D. C. Nos. 17518, 19636. Sample Nos. 35916-H, 35919-H, 56446-H.)

LIBELS FILED: On or about February 28 and April 18, 1946, Western District of Missouri.

ALLEGED SHIPMENT: On or about December 13, 1945, and February 20, 1946, by Killashun Sales Division, from Akron, Ohio.

PRODUCT: Examination of 244 samples in one lot and 100 samples in the other lot showed that 4.5 percent and 5 percent, respectively, were defective in that they contained holes.

LABEL, IN PART: (Portion) "Texide Rubber Sheaths," or "Tetratex Prophylactics."

NATURE OF CHARGE: Adulteration (both lots), Section 501 (c), the quality of the articles fell below that which they purported to possess.

Misbranding (1 lot only), Section 502 (a), the label statements "For Prevention of Venereal Disease" and "Prophylactics" were false and misleading as applied to an article containing holes.

DISPOSITION: August 15, 1946. No claimant having appeared, judgments were entered ordering the products destroyed.

2118. Adulteration and misbranding of prophylactics. U. S. v. 15 Gross, etc.
(F. D. C. No. 19635. Sample Nos. 3706-H, 3707-H.)

LIBEL FILED: April 17, 1946, Western District of Virginia; amended libel filed December 19, 1946.

ALLEGED SHIPMENT: On or about February 12, 1946, by the Crown Rubber Sundries Co., from Akron, Ohio.

PRODUCT: 15 gross and 2 gross of *prophylactics* at Pulaski, Va. Examination of 216 samples of each lot showed that 3.2 percent of one lot and 4.6 percent of the other lot were defective in that they contained holes.

LABEL, IN PART: "Texide Rubber Sheaths," or "Gold-Pak Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the articles were defective in that they contained holes.

Misbranding (Gold-Pak only), Section 502 (a), the label statement "Prophylactics * * * An aid in prevention of disease" was false and misleading.

DISPOSITION: January 10, 1947. The Crown Rubber Sundries Co. having withdrawn its answer and claim, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

2119. Misbranding of Neo-Enzymes Plain and Neo-Enzymes With Laxative. U. S. v. B. Sanders Wilson (Wilco Laboratories). Plea of guilty. Fine, \$200 and costs. (F. D. C. No. 20120. Sample Nos. 28399-H, 28400-H.)

INFORMATION FILED: August 28, 1946, Northern District of Illinois, against B. Sanders Wilson, trading as Wilco Laboratories, Chicago, Ill.

ALLEGED SHIPMENT: On or about March 30, 1945, from the State of Illinois into the State of Washington.

LABEL, IN PART: "Neo-Enzymes Plain A Nutritional Supplement," or "Neo-Enzymes With Laxative An Aid In Digesting Starch, Fats and Proteins Waste Eliminant."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements on the labels (both products) "An Aid In Digesting Starch, Fats and Proteins," (plain) "Neo-Enzymes are supplied for nutritional purposes only to replace enzymes destroyed or lost in heat preparation of foods, or eliminated by the body," and (with laxative) "Neo-Enzymes is a digestive aid," and statements in the circulars entitled "Wilco Neo-Enzymes," which accompanied the articles, were false and misleading since these statements represented, suggested, and created in the mind of the reader the impression that the articles would aid in digesting starch, fats, and proteins; that they would aid impaired digestion and the assimilation of foods; that they would be efficacious in the cure, mitigation, treatment, and prevention of malnutrition, dietary imbalance, disorders arising in the digestive tract and transmitted to various parts of the body, febrile conditions, constipation, and infections such as colds; that they would hasten convalescence from disease or operation or chronic conditions due to glandular or metabolic deficiency; that they would be of value in the treatment of over-acidity and over-alkalinity; that they would enable one to digest over-cooked cabbage; that they would be efficacious in the cure, mitigation, treatment, and prevention of gastritis, dyspepsia, intestinal putrefaction, chronic fatigue conditions, wasting diseases, acne, allergic conditions,

*See also Nos. 2102, 2105-2108, 2110, 2111, 2114, 2118.

and arthritis; that they would relieve indigestion due to bloaty fermentation of foods; that they would normalize the intestinal contents and reduce bacterial formation of toxins, ptomaines, cadaverine, and putrescine; that they would aid food assimilation in old age; that they would enable one to build weight; and that the Neo-Enzymes Plain would replace enzymes destroyed or lost in heat preparation of foods or eliminated by the body. The articles would not be effective for the purposes claimed.

Further misbranding, Section 502 (a), the statements on the labels (both products) were misleading since they failed to reveal the fact that the articles would have little, if any, power to digest starch and proteins, which fact was material in the light of the following representations in the labeling: "Neo-Enzymes digests carbohydrates, proteins and fats—a balanced digestant complex. Effective in acid, alkaline or neutral medium. Amyloclastic Activity By modified Wohlgemuth method; splits 475 times its own weight of soluble starch. Proteolytic Activity By electrotitration and spectrophotometric method; hydrolyzes 680 times its own weight of casein and albumin."

Neo-Enzymes With Laxative. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions displayed on the bottle, provided for continuous use of the article, which was a laxative and should not be used continuously; and, Section 502 (f) (2), the labeling failed to bear adequate warnings against use of the article in those pathological conditions where its use might be dangerous to health. The article was a laxative, and its labeling failed to bear a warning that it should not be used in the presence of symptoms of appendicitis.

The information contained 4 counts, 2 charging violation under the provisions of the law relating to drugs reported in this notice of judgment, and 2 charging misbranding under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On January 9, 1947, the defendant having entered a plea of guilty, the court imposed a fine of \$200 on each count. On January 16, 1947, the fine was reduced to \$100 on each count.

2120. Misbranding of Tyr-Ade. U. S. v. Chester R. Gilliland. Plea of guilty. Defendant placed on probation for a period of 2 years and ordered to pay \$300 in costs. (F. D. C. No. 21430. Sample Nos. 27871-H, 27872-H.)

INFORMATION FILED: January 20, 1947, Northern District of California, against Chester R. Gilliland, Sacramento, California.

ALLEGED SHIPMENT: On or about September 7, 1945, the defendant shipped a bottle of the product from the State of California into the State of Washington, and on September 10, 1945, he shipped a booklet entitled "Health From The Ground Up."

PRODUCT: Analysis showed that the article consisted essentially of mineral matter, including compounds of calcium, iron, iodine, and phosphorus, together with dulse and green, leafy tissue.

LABEL, IN PART: "Tyr-Ade, A Highly Concentrated Food."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Tyr-Ade" on the label of the article was misleading since it represented, suggested, and created in the mind of the reader the impression that the article would be effective in overcoming tiredness and fatigue, whereas it would not be effective for such purposes.

Further misbranding, Section 502 (a), certain statements in the booklet accompanying the article were false and misleading since they represented, suggested, and created in the mind of the reader the impression that the article would save health and life and prevent sickness and death; that it was vital for healthful body functioning; that it was vital to rebuild healthy, normal blood, bones, and tissue, to keep each organ working, to keep health up to par, and to regain health; that it would be an adequate treatment for anemia; that it would prevent a breakdown of kidney cells and decomposition in the walls of the kidneys; that it would prevent dropsy, albuminuria, and other kidney diseases often fatal; that the use of the article by women would prevent tumors, weakness, anemia, and various other female ailments, surgical operations, and hysteria; that the article would normalize the body; that common vegetables are not a satisfactory source of vitamins and minerals; that the deficiencies in manganese, sulfur, copper, sodium, magnesium, potash, and

chlorine represented nutritional problems in this country; that the use of the article would insure against all vitamin and mineral deficiencies; that the article would be effective to prevent and correct lack of vitality, sterility, impotence, neurasthenia, nervousness, sleeplessness, poor memory, impurities of the skin, psychoneurosis enfeeblement of the mind, psychocoma, morning sickness in pregnancy, arteriosclerosis, varicose veins, gout, creaking joints, congestion of the bowels, constipation, arthritis, bone ailments, poor complexion, brain tumors, diabetes, syphilis and other sexual diseases, cancer, obesity, rheumatism, autointoxication, and heart disease; that the article would relax the brain, promote sleep, cool the liver, assuage fever, calm nerve ends and nerve nets, stop certain kinds of heat, soothe the generative system, stop contraction in motor nerves, relieve neurotic cramps, reduce temper, and relieve pain in periosteal structures of the body and in linings containing fine nerves capable of intensive pain sensations; and that it would prevent germs from taking hold, prevent impairment of the lining of the lungs, throat, and bronchial tubes, and prevent and correct tension in the spleen. The article would not be efficacious for the purposes stated and implied.

DISPOSITION: April 30, 1947. The defendant having entered a plea of guilty, the court ordered that he be placed on probation for a period of 2 years and that he pay a sum of \$300 as costs and expenses.

2121. Misbranding of Miracle Slenderizing Cream. U. S. v. Norval C. Douglas (Miracle Products). Plea of not guilty. Tried to the jury. Verdict of guilty. Sentence of 1 year's imprisonment and fine of \$4,000. Judgment reversed on appeal to the Circuit Court of Appeals. Case returned to the district court for retrial. Plea of nolo contendere subsequently entered and a fine of \$2,000 and costs imposed. (F. D. C. No. 14292. Sample Nos. 41208-F, 63480-F.)

INFORMATION FILED: On or about June 20, 1945, Northern District of Illinois, against Norval C. Douglas, trading as Miracle Products at Chicago, Ill.

ALLEGED SHIPMENT: From the State of Illinois into the States of Texas and Georgia. The product was shipped on or about March 2 and May 22, 1944. A number of circulars entitled "The Miracle Plan For A Slender Body" and "For the Preservation and Enhancement of Beauty" were shipped with a portion of the product, and a number of the circulars were shipped separately on or about April 26, 1944.

PRODUCT: Examination showed that the product was a semi-solid, consisting essentially of water, magnesium stearate, epsom salt, and sodium sulfate, perfumed with methyl salicylate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the product was false and misleading since it represented and suggested that the article would be efficacious in the reduction of body weight, whereas it would not be efficacious for such purpose.

The information charged also that another product, *Miracle Aid*, was misbranded under the provisions of the law applicable to cosmetics, as reported in notices of judgment on cosmetics.

DISPOSITION: The defendant having entered a plea of not guilty, the case came on for trial before a jury on December 3, 1945. The jury returned a verdict of guilty. The court thereupon sentenced the defendant to serve 1 year in jail, and imposed a fine of \$1,000 on each of the 4 counts of the information. The case was subsequently appealed to the United States Circuit Court of Appeals for the Seventh Circuit, and on June 15, 1946, the following opinion was handed down by that court:

MAJOR, Circuit Judge: "This is an appeal from a judgment of conviction predicated upon an information filed by the United States District Attorney, which charged a violation of numerous sections of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. 301, et seq.

"Defendant urges numerous grounds for reversal, but inasmuch as we are of the view that the judgment must be reversed on one of such grounds, it is unnecessary to state or discuss the others. The court sent to the jury the information, to which were attached two affidavits, each of which contained convincing proof in support of the charges contained in the information. One of the affidavits was made by a person called as a witness at the trial, the other was not. We see no reason to set forth the contents of these affidavits.

It is sufficient to state that they strongly supported the government's case; in fact, they contained proof of every element essential to a conviction.

"The question therefore is, was the submission of these affidavits to the jury reversible error? The government attempts to excuse their submission almost entirely by the fact that the court instructed the jury in the usual form to the effect that the information was no evidence of the defendant's guilt, that it was not to be treated by the jury as raising any kind of presumption against the defendant, and that it was simply the formal manner prescribed by law for preferring a charge and should be regarded by the jury solely in that light. A number of cases are cited in which this general instruction has been approved. We need not cite or discuss them for the reason that they are beside the point. No complaint is made because the information was permitted to go to the jury, but the criticism is directed solely at the affidavits. It is one thing to send to the jury an indictment or information, the accusation against the defendant, but something entirely different to send affidavits containing the government's proof in support of such accusation. We know of no authority and we suspect there is none which condones, much less approves, such a procedure.

"It is pointed out by the government that these affidavits were required by the court as a prerequisite to its granting leave to file the information. This no doubt was a proper procedure. The filing of an information is discretionary with the court and leave must be obtained. In the exercise of this discretion, it may properly require that in some manner it be satisfied of probable cause for a prosecution. One of the ways by which it may be so satisfied is by the filing of affidavits. See *Albrecht v. United States*, 273 U. S. 1, 5.

"It is also suggested that the affidavits were attached to the information and became a part thereof. We are unable to discern how this affects the situation. We know of no reason why they should be attached to the information other than perhaps for the purpose of convenience. In any event, they are no part of the charge, and their sole function is to serve as proof in convincing the court that leave should be granted to file. Furthermore, the fact that they were attached to the information furnishes no reason why they could or should not have been detached before the information was sent to the jury.

"The government is in a dilemma in attempting to sustain its position. In one breath it concedes, as it must, that these affidavits were submitted to the court as proof in support of the charge for the purpose of inducing the court to grant leave to file, and in the next breath argues that when these same affidavits were submitted to the jury they were merely a part of the accusation and constituted no proof in support thereof. This latter argument is untenable and must be rejected. In fact, we think that there would be no difference in effect or result if the transcript of the testimony given before a grand jury as the basis for an indictment was submitted to the trial jury. Surely no one would seriously contend but that such procedure would constitute prejudicial error.

"Lastly, the government urges that this court ignore the error for the reason that it was neither excepted to nor assigned as error by the defendant. Again the government is in a rather awkward situation. There is nothing in the record, including the court's charge to the jury, to show or indicate that either defendant or the court had any knowledge that these affidavits were being submitted to the jury. The court instructed the jury concerning the information and of course all had knowledge that it was being submitted. Obviously, defendant's counsel could not be expected to object to the submission of the affidavits unless he had knowledge thereof. True, as pointed out, the court no doubt had knowledge that the affidavits were attached to the information at the time leave was granted to file, but it does not follow that it had such knowledge at the time it submitted the information. Furthermore, it may be that the court presumed that counsel for the government would make it his business, as he should have done, to ascertain that these affidavits were detached. Counsel for the government was the moving factor in the matter and must be held responsible for a procedure which, in our judgment, was unfair, prejudicial and attended with dangerous consequences.

"Furthermore, we are of the view that the question presented is too serious to go unnoticed even though it was not properly raised in the court below. Amendment VI of the Constitution of the United States provides: 'In all criminal prosecutions, the accused shall enjoy the right * * * to be confronted with the witnesses against him.' The submission to the jury of the

affidavits complained of was a palpable infringement of this constitutional right.

"The judgment is REVERSED."

A petition for rehearing was filed, and following its denial on July 6, 1946, the case was returned to the district court. On February 25, 1947, the defendant entered a plea of nolo contendere, on which date the court imposed a fine of \$2,000 and costs, which included charges against both the drug and cosmetic.

2122. Misbranding of Miracle Milk Bath, Miracle Bath, Miracle Cream, and Miracle-Aid Lotion. U. S. v. 54 Bags, etc. (and 1 other seizure action). (F. D. C. Nos. 19700, 21194. Sample Nos. 51572-H, 56441-H to 56444-H, incl.)

LIBLES FILED: On or about April 26 and October 16, 1946, Western District of Missouri and District of Minnesota.

ALLEGED SHIPMENT: Between the approximate dates of March 5 and 15, and on or about September 17, 1946, by the Marval Laboratories, Inc., from Chicago, Ill.

PRODUCT: 54 6-pound bags of *Miracle Milk Bath*, 11 6-pound bags of *Miracle Bath*, 15 1-pound jars of *Miracle Cream*, and 62 6-fluid-ounce bottles of *Miracle-Aid Lotion* at Kansas City, Mo., and 22 1-pound jars of *Miracle Cream* at Minneapolis, Minn. Examination showed that the *Miracle Milk Bath* consisted essentially of epsom salt and skim milk powder; that the *Miracle Bath* consisted essentially of epsom salt, sulfur, and soap; that the *Miracle Cream* consisted essentially of epsom salt, sodium sulfate, water, fatty acids, and methyl salicylate; and that the *Miracle-Aid Lotion* consisted essentially of water, with small proportions of soapy material, gum, and perfume.

NATURE OF CHARGE: Misbranding, Section 502 (a), (*Miracle Milk Bath* and *Miracle Cream*) the label statement "An Aid for Reducing" was false and misleading since the articles would not be effective to bring about a reduction in weight; (*Miracle Bath*) the label statements "A Reducing Aid for Home Use * * * Aid for Rheumatism and Arthritis" were false and misleading since the article would not be effective in reducing and in the treatment of rheumatism and arthritis; and (*Miracle-Aid Lotion*) the label statements "For Superficial Wrinkles * * * Applied by Patting with Fingertips, on Wrinkles" were false and misleading since the article would not be effective in the removal of wrinkles.

DISPOSITION: August 15, 1946, and March 6, 1947. No claimant having appeared, judgments were entered ordering that the products be destroyed.

2123. Misbranding of Miracle Bath, Miracle Cream, and Miracle-Aid Lotion. U. S. v. 34 Packages, etc. (F. D. C. No. 22304. Sample Nos. 68051-H to 68054-H, incl., 68072-H to 68074-H, incl.)

LIBLE FILED: March 3, 1947, District of Nebraska.

ALLEGED SHIPMENT: On or about February 14, 1947, by Valmar Distributors, Inc., Chicago, Ill., from Milwaukee, Wis.

PRODUCT: 34 6-pound packages of *Miracle Bath*, 28 1-pound jars of *Miracle Cream*, and 8 6-fluid-ounce bottles of *Miracle-Aid Lotion* at Omaha, Nebr. Analyses showed that the *Miracle Bath* consisted essentially of epsom salt, sulfur, and soap; that the *Miracle Cream* consisted essentially of epsom salt, sodium sulfate, water, fatty acids, and methyl salicylate; and that the *Miracle-Aid Lotion* consisted essentially of water, with small portions of soapy material, gum, and perfume.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain label statements on the articles were false and misleading. The statement "A Reducing Aid * * * for Rheumatism and Arthritis," appearing on the label of the *Miracle Bath*, represented and suggested that the article would be effective in reducing and in the treatment of rheumatism and arthritis; the statement "An Aid for Reducing," appearing on the label of the "*Miracle Cream*," represented and suggested that the article would be effective to bring about a reduction in weight; and the statement "For Superficial Wrinkles * * * Apply by patting with finger tips, on wrinkles," appearing on the label of the *Miracle-Aid Lotion*," represented and suggested that the article would be effective in the removal of wrinkles. The articles would not be effective for such purposes.

DISPOSITION: April 11, 1947. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

2124. Misbranding of Menstruaid. U. S. v. 4 Packages * * *. (F. D. C. No. 19814.
Sample No. 38152-H.)

LIBEL FILED: May 22, 1946, Northern District of Illinois.

ALLEGED SHIPMENT: On or about March 3, 1946, by the H. K. Drug Co., from Dubuque, Iowa.

PRODUCT: 4 packages of *Menstruaid* at Chicago, Ill. Each package contained five products.

LABEL, IN PART: (Packages) "Menstruaid H. K. Pharmaceutical Laboratories, Dubuque, Iowa"; (separate products) "Menstruaid No. 1 Contents Estrogen (Estrus Producing Hormone) Ergot Cotton Root Alcohol 35%," "Menstruaid No. 2 Contents Aloes," "Menstruaid No. 3 * * * Contents Tetra Sodium Pyrophosphate," "Menstruaid No. 4 * * * Contents * * * Water Pepper," and "Menstruaid No. 5 Contents * * * Boroglyceride Estrogen (Estrus Producing Hormone)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label designation *Menstruaid* was false and misleading since it represented and suggested that the article would be effective in the relief of menstrual disorders. The article would not be effective for such purposes.

DISPOSITION: August 5, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Food and Drug Administration.

2125. Misbranding of Rhu-Aid. U. S. v. 57 Cartons * * *. (F. D. C. No. 22391.
Sample No. 42102-H.)

LIBEL FILED: January 16, 1947, Southern District of West Virginia.

ALLEGED SHIPMENT: On or about December 18, 1946, by the Rhu-Aid Medicine Co., from Cincinnati, Ohio.

PRODUCT: 57 cartons, each containing 1 8-fluid-ounce bottle, of *Rhu-Aid* at Charleston, W. Va. Analysis showed that the product consisted essentially of sodium salicylate (14.3 grains per fluid ounce), potassium iodide, potassium citrate, and water.

LABEL, IN PART: "Rhu-Aid A Liquid Analgesic."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Rhu-Aid * * * for relief of rheumatic symptoms such as muscular aches and pains * * * muscular lumbago" were false and misleading since the article would not be effective for muscular aches and pains caused by rheumatism or for muscular lumbago.

DISPOSITION: March 31, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2126. Misbranding of Medicone Emmenagogue. U. S. v. 44 Boxes * * *. (F. D. C. No. 20225. Sample No. 56885-H.)

LIBEL FILED: June 13, 1946, District of Rhode Island.

ALLEGED SHIPMENT: On or about April 12, 1946, by the Medicone Co., from New York, N. Y.

PRODUCT: 44 Boxes of *Medicone Emmenagogue* at Providence, R. I. Analysis showed that the product consisted essentially of a laxative plant drug such as aloes, reduced iron, and asafoetida, coated with calcium and magnesium carbonates.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label designation "Emmenagogue" was false and misleading since the article was not an emmenagogue.

DISPOSITION: December 4, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2127. Misbranding of Syntenon. U. S. v. 5 Boxes * * *. (F. D. C. No. 22252.
Sample No. 54269-H.)

LIBEL FILED: February 10, 1947, Southern District of Florida.

ALLEGED SHIPMENT: On or about December 31, 1946, by Sumlar Co., from Brooklyn, N. Y.

PRODUCT: 5 60-capsule boxes of *Syntenon* at West Palm Beach, Fla. Analysis showed that the product had the composition stated on its label.

LABEL, IN PART: "Syntenon * * * Each capsule contains Ephedrine Sulphate 0.02 gm., Vitamin C (Ascorbic Acid) 2,000 U. S. P. Units, with small quantities of Calcium Lactate."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "For mitigating symptoms of hay fever, asthma and sinus distress due to vitamin C deficiency" were false and misleading because hay fever, asthma, and sinus distress are not due to vitamin C deficiency, and, further, because the article would not be effective for mitigating sinus distress.

DISPOSITION: March 13, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2128. Misbranding of Dorel. U. S. v. 82½ Dozen Packages, etc. (F. D. C. No. 21233. Sample No. 32169-H.)

LIBEL FILED: October 14, 1946, Southern District of California.

ALLEGED SHIPMENT: Between the approximate dates of March 13 and August 1, 1946, by the Sutter Chemical Co., from Altoona, Pa.

PRODUCT: 82½ dozen packages, each package containing 126 tablets, and 572 dozen packages, each package containing 42 tablets, of *Dorel* at North Hollywood, Calif.

LABEL, IN PART: "Dorel * * * Each Tablet contains: Aspirin (Acetyl Salicylic Acid) 4 grs. Acetophenetidin .75 grs. Vitamin D (Activated Ergosterol) 5,000 USP Units Vitamin B₁ 1 mg. * * * Distributed by Durneck Co. Los Angeles, Calif."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the carton and bottle labels and in a leaflet enclosed in the carton were false and misleading since they represented and suggested that the article would be effective in the relief of pains associated with rheumatism, arthritis, neuritis, and lumbago; that it would be effective to relieve disturbances of vitamin deficiency and poor health associated with such conditions; and that it was a new and especially prepared formula for such conditions. The article would not be effective for these purposes, and it was not a new and especially prepared formula for such conditions.

DISPOSITION: November 25, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2129. Misbranding of Autry's Minerals. U. S. v. 1,400 Packages, etc., and a quantity of letters and booklets. (F. D. C. No. 20714. Sample No. 67303-H.)

LIBEL FILED: August 16, 1946, District of Kansas.

ALLEGED SHIPMENT: The packages of the product were shipped by Natural Minerals Company, from Hollywood, Calif., on or about June 12, 1946. The letters and booklets were shipped on or about June 28 and July 11, 1946, respectively, from Denver, Colo., on instructions from the Natural Minerals Co.

PRODUCT: 1,400 \$10-size packages and 1,000 \$5-size packages of *Autry's Minerals*, and a quantity of form letters headed "The Mineral Sales Co., Inc." and several thousand booklets entitled "To Your Health" at Wichita, Kans.

LABEL, IN PART: (Carton) "Ingredients: Dicalcium Phosphate, Ferrous (Iron) Sulphate, Potassium Iodide and a natural sedimentary Mineral deposit consisting essentially of carbonaceous material and the oxides of silicon with small amounts of other mineral oxides with excipients and sugar coating."

It was represented in the labeling that the basic ingredients of the article were obtained from a mineral deposit in the Western mountains.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements appearing in the circular letter and booklet accompanying the article were false and misleading. These statements represented, suggested, and created the impression in the mind of the purchaser that the user of the article could be surer of a normally functioning system; that the article would alleviate pain and suffering and produce happiness and health; that it was a necessary factor for the retention and development of health; that it was essential as a supplement to the diet; that it would effect normality of the blood stream and thereby strong, healthy body tissues and a fine healthy body; that it would prevent sickness, suffering, lowered resistance to disease, and a shortening of life; that it would be effective for anemic conditions, headaches, fatigability, tiredness, diz-

ziness, loss of appetite, weakened heart, and worrisome conditions of the blood stream; that it would prevent disease and deaths among children under ten years of age; that it would enable expectant mothers to give birth to strong, healthy infants; that it would correct numerous morbid conditions and diseases, including bone deformities, bad teeth, nervous disorders, reduced resistance to other diseases, affections of the nose and throat, swollen glands, enlarged and diseased tonsils, defective vision, round shoulders, bow legs, and behavior disturbances, such as incorrigibility, assaultiveness, and nonadaptability; that it would favorably influence growth and development, both mental and physical, of children; that it would effect proper functioning, stability, and building of the nerves; that it would aid in correcting the evils of constipation; that it would help to remedy the ravages of time and disease; and that it would give life. The article would not be effective for such purposes.

Further misbranding, Section 502 (a), additional statements in the booklet accompanying the article were false and misleading. These statements represented and suggested that the constituents of the tablets obtained from a mineral deposit in the Western mountains supplies the calcium, phosphorus, iron, and iodine ingredients of the preparation. The ingredients from the Western mountains did not supply significant proportions of calcium, phosphorus, iron, and iodine, or any nutritionally or therapeutically useful ingredient. The calcium, phosphorus, iron, and iodine ingredients of the article were supplied by chemical compounds from other sources.

DISPOSITION: November 18, 1946. The Mineral Sales Co., Inc., Wichita, Kans., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond, conditioned that it be relabeled under the supervision of the Federal Security Agency. The booklets and form letters were destroyed in the process of relabeling.

2130. Misbranding of Supermax Multiple Vitamins. U. S. v. 72 Bottles * * * and 200 circulars. (F. D. C. No. 21963. Sample No. 67284-H.)

LIBEL FILED: December 12, 1946, District of Nebraska.

ALLEGED SHIPMENT: On or about October 7, 1946, by Vitamin House, from Birmingham, Ala.

PRODUCT: 72 bottles of *Supermax Multiple Vitamins* and 200 circulars entitled "New Exciting Vigor" at Omaha, Nebr.

LABEL, IN PART: "Supermax 100 Capsules Multiple Vitamins Each Spheroid Gelatin Capsule Contains: Vitamin A 5000 USP Units, Vitamin D 1000 USP Units, Vitamin B₁ 1665 USP Units, Vitamin B₂ 3000 Micrograms, Vitamin B₆ 50 Micrograms, Vitamin C 1000 USP Units, Calcium Pantothenate Dextrorotatory 1000 Micrograms, Niacinamide 25 Milligrams."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements appearing in the circular were false and misleading: "New Exciting Vigor And Radiant Health Can Be Yours! No longer is it necessary to suffer from fatigue, nervous irritability, colds, poor appetite, and that tired, listless feeling, when due to a vitamin deficient diet. Pep up! Find new health and happiness! Enrich your diet with amazing 'Dynamo-of-Energy' vitamins that pack a real wallop to that run down, knocked-out feeling, * * * for an exciting new lease on life! Wake up each morning wonderfully, vigorously Alive! * * * The chances are that you are not getting all you should. * * * You, too, can find abundant new vitality and prolonged prime of life * * * Get Super Strength * * * and thrill to the wonder of New, Sparkling Health and Dynamic Living * * * Activity can be the spice of your life!" These statements represented and suggested that the article would be effective to prevent and correct fatigue, nervousness, irritability, colds, poor appetite, tiredness, listlessness, and run-down conditions; that it would be effective to insure vitality, vigor, and radiant health; and that the average individual in this country requires additional vitamins. The article would not be effective for the conditions named, and the average individual in this country does not require vitamins in addition to those supplied by the ordinary diet.

The article was misbranded also under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 29, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2131. Misbranding of Colusa Natural Oil and Colusa Natural Oil Capsules. U. S. v. 212 Bottles, etc., and a printed sheet for druggists. (F. D. C. No. 22294. Sample Nos. 14924-H, 39530-H.)

LIBEL FILED: March 6, 1947, Eastern District of Wisconsin.

ALLEGED SHIPMENT: By the Colusa Remedy Co., from Los Angeles, Calif., and Chicago, Ill. Bottles of the product were shipped on or about December 14, 1946, and the packages of capsules were shipped on or about January 20, 1947. The printed sheet for the use of druggists was shipped by mail on or about December 18, 1946.

PRODUCT: 141 2-fluid-ounce bottles and 71 4-fluid-ounce bottles of *Colusa Natural Oil* and 136 100-capsule packages and 72 200-capsule packages of *Colusa Natural Oil Capsules*, and a printed sheet of advertising, at Milwaukee, Wis. Examination of both articles showed that they consisted of crude petroleum oil.

NATURE OF CHARGE: Misbranding, Section 502 (a), (*Colusa Natural Oil*) the label statement "for open sores" was false and misleading since it represented and suggested that the article would be effective as a remedy for open sores, whereas it would not be effective for such purposes; (*Colusa Natural Oil Capsules*) certain label statements contained in the printed sheet entitled "What Druggists Want to Know About Colusa Natural Oil and Natural Oil Capsules An Unrefined Rare Oil from the Earth" were false and misleading since they represented and suggested that the article would be effective for eczema, psoriasis, skin diseases, and leg ulcers; and (both products) that the articles were regarded by the medical profession as having merit in the treatment of the diseased conditions mentioned. The articles would not be effective for such purposes, and they are not regarded by the medical profession as having merit in the treatment of these diseased conditions.

DISPOSITION: April 23, 1947. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

2132. Misbranding of Creme-A-Tone. U. S. v. 58 Dozen Bottles * * *. (F. D. C. No. 19852. Sample No. 49402-H.)

LIBEL FILED: On or about May 20, 1946, Northern District of Texas.

ALLEGED SHIPMENT: On or about March 4, 1946, by Oxford Products, Inc., from Cleveland, Ohio.

PRODUCT: 49 dozen 16-ounce bottles and 9 dozen 32-ounce bottles of *Creme-A-Tone* at Dallas, Tex. Examination showed that the article consisted of aluminum hydroxide gel.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "For * * * Peptic ulcer relief" was false and misleading since the article was not effective for peptic ulcer relief.

DISPOSITION: June 24, 1946. Oxford Products, Inc., claimant, having admitted the facts in the libel, judgment of condemnation was entered and the product was ordered released under bond, conditioned that it be relabeled in compliance with the law, under the supervision of the Food and Drug Administration.

2133. Misbranding of Tescum Powders. U. S. v. 24 Packages * * *. (F. D. C. No. 20071. Sample No. 18119-H.)

LIBEL FILED: October 15, 1946, Northern District of Illinois.

ALLEGED SHIPMENT: On or about January 8, 1946, by the Tescum Co., from Cleveland, Ohio.

PRODUCT: 24 packages each containing 14 *Tescum Powders* at Chicago, Ill. Examination showed that the article consisted essentially of tartar emetic, ammonium chloride, gold and sodium chloride, and sugar.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Chronic Alcoholism is medically recognized as a disease" was false and misleading. This statement represented, suggested, and created the impression that the article would be effective in the treatment of alcoholism, whereas it would not be effective for such purpose. The name *Tescum Powders* on the label was misleading since the name had been associated for many years with a product represented as a treatment for alcoholism.

DISPOSITION: January 30, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2134. Misbranding of I-Odoral Ointment. U. S. v. 34 Jars * * * and 1 display card. (F. D. C. No. 21213. Sample No. 53037-H.)

LIBEL FILED: October 4, 1946, Northern District of Ohio.

ALLEGED SHIPMENT: On or about April 26, 1946, by the C. L. S. Products Corporation, from Pittsburgh, Pa. The display card was delivered by a representative of the shipper on or about April 19, 1946.

PRODUCT: 34 Jars of *I-Odoral Ointment* and a display card entitled "Try *I-Odoral* for External Skin Conditions" at Cleveland, Ohio. Analysis showed that the product consisted essentially of mercurous chloride (calomel) 4.57 percent, zinc oxide, and thymol iodide, in an ointment base.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements on the jar and carton labels, "Acne Dry Eczema * * * Impetigo Ringworm * * * and other common external skin conditions," the statements and designs on the display card, "For External Skin Conditions Ringworm Ecthyma Psoriasis Acne Erythema Nodosum Scabies * * * Impetigo Contact Eczema Barbers Itch," and a design showing pictures of these conditions were false and misleading since the statements and designs represented and suggested that the product would be effective in the treatment of acne, dry eczema, impetigo, ringworm and other common external skin conditions, ecthyma, psoriasis, erythema nodosum, scabies, contact eczema, and barber's itch, whereas the product would not be effective in the treatment of these conditions; and, Section 502 (e) (2), the label failed to bear the common or usual name of each of the active ingredients in the article, since the presence of zinc oxide had not been revealed in the labeling, and since the label failed to bear a statement of the quantity or proportion of calomel, a derivative of mercury, present in the product.

DISPOSITION: November 8, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2135. Misbranding of Adiron, B Family Factors, StafTabs, and Swiss Kriss Brand Herbal Laxative. U. S. v. 154, 214, and 180 Bottles, etc., and accompanying literature. (F. D. C. No. 20558. Sample Nos. 17282-H to 17285-H, incl.)

LIBEL FILED: August 9, 1946, Northern District of Illinois.

ALLEGED SHIPMENT: Between the approximate dates of February 9, 1946, and June 13, 1946, by Modern Products, Inc., from Milwaukee, Wis.

PRODUCT: Above-named quantities of drugs at Chicago, Ill. A number of circulars entitled "The New Blood Building Diet," "Fighting Fatigue with Diet," "Your Diet and Your Nerves," "Comfortable Relief For You in Swiss Kriss For Constipation," "The Original 7-Day Elimination Diet," and "The New Zig-Zag Reducing Diet" accompanied the articles.

LABEL, IN PART: "Adiron For Iron Deficiency Anemia * * * Each tablet contains 24 milligrams of iron in nutritionally available form," "B Family Factors of the B family as contained in brewer's yeast especially cultured with corn, biologically processed with clostridium acetobutylicum, and fortified with niacin amide, riboflavin and thiamin," "StafTabs * * * Each tablet contains: 80 milligrams Calcium, 60 milligrams Phosphorus, 100 U. S. P. XI Units Vitamin D," or "Swiss Kriss Brand Herbal Laxative."

NATURE OF CHARGE: *Adiron*. Misbranding, Section 502 (a), the statements in the accompanying circulars entitled "The New Blood Building Diet" and "Fighting Fatigue with Diet" were false and misleading since they represented and suggested that the article was an adequate treatment for pale lips and ear lobes and constant tiredness and fatigue, and that most iron-containing foods, unlike *Adiron*, do not supply iron in assimilable form. The article would not be an adequate treatment for these conditions, since they are often due to causes not remediable by the use of *Adiron*, and most iron-containing foods supply iron in assimilable form.

B Family Factors and *StafTabs*. Misbranding, Section 502 (a), the statements in the leaflets entitled "Your Diet and Your Nerves" and "Fighting Fatigue with Diet" were false and misleading since they represented and suggested that the products, together with other food factors, would be effective for nervous, upset, and angry conditions, fatigue, and inability to think clearly and to get things done properly and quickly. The articles would not be effective for such purposes.

Swiss Kriss Brand Herbal Laxative. Misbranding, Section 502 (a), the statements in the leaflets entitled "Comfortable Relief For You in Swiss

Kriss For Constipation," "The Original 7-Day Elimination Diet," and "The New Zig-Zag Reducing Diet" were false and misleading since they represented that the product had value in reducing body weight; that its use twice a year for a week at a time would be in the interest of maintaining health; that it would keep one physically fit in times of nervous stress and extraordinary demands; that it would enable the user to enjoy life and be "regular"; that it would prevent the user being sluggish, depressed, cranky, unhappy, dull, listless, or tired; and that it would bring quick, pleasant, and effective relief from headache and finicky appetite. The article would not be efficacious for such purposes. Further misbranding, Section 502 (c), the information required by law to appear on the label was not prominently placed thereon in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the fact was not revealed that the active ingredient of the product upon which its laxative properties depended was senna.

DISPOSITION: October 23, 1946. Modern Products, Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered, and the products were ordered released under bond to be relabeled. Further, all literature not in compliance with the Federal Food, Drug, and Cosmetic Act was ordered destroyed under the supervision of the Food and Drug Administration.

2136. Misbranding of electric light bulbs. U. S. v. Archibald H. Roberts. Plea of guilty. Fine, \$25. (F. D. C. No. 20179. Sample Nos. 27022-H, 36781-H.)

INFORMATION FILED: October 24, 1946, District of Minnesota, against Archibald H. Roberts, Minneapolis, Minn.

ALLEGED SHIPMENT: Between the approximate dates of November 22, 1944, and June 11, 1945, from the State of Minnesota into the State of Montana.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular entitled "A New Scientific Development" and on printed placards headed "Now! Deep Infra-Red Ray From Any Light Socket," which were shipped with the article, were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of prostatic troubles, sprains, sinus trouble, neuralgia, rheumatism, lumbago, neuritis, pleurisy, pneumonia, tonsillitis, influenza, arthritis, bronchitis, catarrh, asthma, fractures, women's ailments, deafness, ear trouble, skin diseases, torticollis, boils when open, cholecystitis, endocarditis, and low red blood count; that it would be efficacious to raise lowered vitality, improve the nervous system, relieve pain, improve circulation, promote absorption of exudate, and increase red blood count; that it would be efficacious in the treatment of superficial conditions, such as infections, acute inflammations, and deep-seated lesions; that it was a general systematic treatment, and would tend to induce active circulation; and that it would be efficacious for many other purposes. The product would not be efficacious for the purposes represented.

DISPOSITION: November 12, 1946. A plea of guilty having been entered, the court imposed a fine of \$25.

2137. Misbranding of gynecological syringes. U. S. v. 39 Packages * * * (F. D. C. No. 22283. Sample No. 67965-H.)

LIBEL FILED: February 12, 1947, Eastern District of Oklahoma.

ALLEGED SHIPMENT: On or about October 17, 1946, by the Walter E. Dewey Company, from Philadelphia, Pa.

PRODUCT: 39 packages containing *gynecological springs* with accessory parts at Sulphur, Okla.

LABEL, IN PART: "Dew-E-Way Gynecological Syringe for Health Safety Convenience."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Dew-E-Way" and certain statements in the accompanying booklet entitled "Dew-E-Way Self-Help for Women" and in the leaflet entitled "The Dew-E-Way for Health and Complete Cleanliness" were false and misleading since they represented and suggested that the article would be effective to promote health, to cure and prevent diseases of women, to remove germs, to remove all odors, to relieve pain, sleeplessness, loss of appetite, nausea, languor, indifference,

dullness over the eyes, and urination difficulties. The article would not be effective for such purposes.

DISPOSITION: April 16, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2138. Misbranding of Depolaray (device). U. S. v. 1 * * * and a number of circulars. (F. D. C. No. 18475. Sample No. 24542-H.)

LIBEL FILED: December 3, 1945, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about June 5, 1945, by the College of Electronic Medicine, from San Francisco, Calif.

PRODUCT: 1 *Depolaray* (device) and a number of circulars entitled "General Reflex Centers and Visceral Centers in Spine" and "Depolaray Procedures" at New Orleans, La. Examination showed that the device consisted essentially of a weak electromagnet operated from a light circuit and equipped with a mechanism intended to produce a vibrating noise.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading since they represented and suggested that the device would be effective in the treatment of the diseases, conditions, and symptoms stated and implied, whereas it would not be effective for such purposes. The statements in the accompanying circulars represented and suggested that the device would be effective in the treatment of acid stomach, appendicitis, arthritis deformans, cerebral abscess, renal colic, colitis, cystitis, catarrhal deafness, diarrhea, abdominal and cardiac dropsy, duodenal ulcer, earache, fecal obstruction, gallstones, gastric ulcer, gastritis, gastroduodenitis, glaucoma, goiter, and hay fever; biliary, neuralgic, ocular, and uterine headache; herpes zoster (shingles), hiccup, hysteria, hystero-epilepsy, impacted gall duct, impotence, incontinence of urine, and infantile paralysis; general inflammation and inflammation of bladder, bowel, bronchi, kidneys, larynx, lungs, meninges, ovaries, pharynx, pleura, stomach, and uterus; influenza, intestinal neuralgia, insomnia, iritis, jaundice, lactation disorders, lacunar tonsillitis, la grippe, laryngeal paralysis, laryngeal stridulous, laryngitis, leukemia, leucorrhea, lobar pneumonia, lockjaw, lumbago, lumbo-abdominal neuralgia, mastoiditis, measles, memory disorders, meningitis, micturition, migraine, movable kidney, mucous colic, mumps, nephritis, trigeminal and brachial neuralgia, neuralgia of the feet, nodding spasm, optic atrophy, optic neuritis, ovarian diseases, palpitation, pancreatic calculi, pancreatic hemorrhage, pancreatitis, paralysis agitans, paralysis crural and facial, parotitis, pellagra, pericarditis, peritonitis, pertussis, pharyngitis, pleurisy, pneumonia, prolapsed kidney, prolapsed uterus, prostatic diseases, ptosis of eyelid, pyelitis, quinsy, rectal fistula, rectal neuralgia, rectal hemorrhage, retinitis, rheumatic fever, rheumatism, sciatica, sneezing, softening of brain, splenitis, splenoptosis, stomatitis, suppression of urine, arterial tension, pendulous testicle, tetanus, tic douloureux, tonsillitis, toothache, toxic gastritis, typhoid fever, typhus fever, uremia, urethritis, uterine catarrh, utero-version, vaginitis, valvular lesions, vomiting, pernicious whooping cough, writer's cramp, stomach worms, wry neck, abdominal gas pains, appendix pains, arm pain or distress, asthma, backache, bladder distress, boils, bowel stoppage, bruises, bronchitis, bursitis, charleyhorse, colds, digestive distress, fractures, gall bladder distress, hemorrhoids or piles, high blood pressure, hip pointers, lumbago, lymphatic gland enlargement, pleurisy pain, shin splints, shoulder distresses, sinusitis, sprains, strains, strep or sore throat, impaired or lost voice, and spastic sphincter; and derangements of the appendix, bladder, bronchi, diaphragm, gall bladder, heart, mammary gland, small intestines, kidneys, larynx, thyroid gland, liver, lungs, ovaries and testes, stomach, and uterus.

DISPOSITION: April 7, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Food and Drug Administration.

2139. Misbranding of Vapo-Path (device). U. S. v. * * * and various appliances and literature (and 1 other seizure action). (F. D. C. Nos. 19694, 19957. Sample Nos. 3000-H, 53208-H.)

LIBELS FILED: April 18 and May 25, 1946, District of Columbia and Western District of Kentucky.

ALLEGED SHIPMENT: On or about October 29, 1945, and February 19, 1946, by the Consolidated Manufacturing Co., from Dayton, Ohio.

PRODUCT: 1 *Vapo-Path* (device) with appliances and various drugs and a number of leaflets entitled "Be a Millionaire In Your Home Town" and booklets entitled "Vapo Path Must Be Good" at Washington, D. C.; also 1 *Vapo Path* (device) with similar appliances and drugs and a number of booklets entitled "Vapo Path Must Be Good" at Murray, Ky.

The device consisted of an electric- or gas-heated, thermostatically-controlled generator and the following appliances: Bath cabinets, metal and canvas masks, enamel and metal foot and leg baths, metal hoods for applying vapor locally to the body, plumbing connections and fittings, and a trough to collect condensed vapors. With the outfit seized at Washington, D. C., were 2 electrically-heated vaporizers called "Vapo Aids." The drugs contained minerals and volatile substances.

Steam produced in the generator would pass over various plates containing the drugs, and it was alleged in the labeling that the steam would "Steam Distill" the drugs. The appliances were for the purpose of applying this steam to the part to be treated. The vapors would become permeated with some of the volatile substances, principally naphthalene, but would contain no minerals.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying leaflets entitled "Be a Millionaire In Your Home Town" and the booklets entitled "Vapo Path Must Be Good" were false and misleading. These statements represented and suggested that the device and the drugs would be effective for arthritis, diabetes, poor elimination, poor circulation, lack of minerals in the body, illness, abscess on the lung, continuous cough, sleeplessness, loss of weight, rheumatism, disease of the stomach and kidneys, bad heart conditions, muscular rheumatism, accumulation of poisons in the system, improper elimination, inflammatory rheumatism, nervousness, stiff joints, melancholia, blood poisonings, swelling of eyes, hands, and knees, infection of the sciatic nerve, acidosis, rash, abscesses, high and low temperatures, decay of the jawbone and sinus, poison in the system, slow kidney action, acid condition, lazy liver, bloating, hay fever, incurable, hopeless, and serious physical conditions, illness in general, numerous conditions of almost every description, and whatever is wrong. The statements in the labeling represented further that the articles would be effective for straightening out the difficulties with which the human system may be struggling, would supply those elements in which the body may be deficient, would attack the basic cause of the vast majority of ailments, and would be effective to prevent serious illness, correct improper conditions, keep one fit, buoyant, and in good health, supply beneficial mineral fumes, and correct deficiencies of the human system. The device and drugs would not be efficacious for the purposes represented and suggested.

DISPOSITION: August 16 and November 13, 1946. *Vapo Path, Inc.*, Dayton, Ohio, having appeared as claimant in both actions, and Miss Frances Bradley having appeared also as claimant in the Kentucky action, and the claimants having consented to the entry of decrees, judgments of condemnation were entered and the articles were ordered released under bond to be destroyed or brought into compliance with the law, under the supervision of the Federal Security Agency.

2140. *Pso-Ridisal*. Suit for injunction. Fred B. Collier and Dianne I. Collier (Nu-Basic Products Co.) v. Paul V. McNutt, Federal Security Administrator, et al. Complaint dismissed.

On September 20, 1944, Fred B. Collier and Dianne I. Collier, trading as the Nu-Basic Products Co., at Royal Oak, Mich., filed a petition for an injunction against Paul V. McNutt, Federal Security Administrator, Paul B. Dunbar, Commissioner of the Food and Drug Administration, and George P. Lerrick, Acting Commissioner of the Food and Drug Administration. The complainants petitioned that the defendants and their agents be restrained and enjoined from instituting legal proceedings with respect to the complainants' product known as *Pso-Ridisal*.

A motion to dismiss the action and for summary judgment was filed on behalf of the defendants. On November 7, 1944, the court entered an order granting such motion, and in connection with such order, made the following findings of fact and conclusions of law:

MATTHEW F. MCGUIRE, *District Judge*:

FINDINGS OF FACT AND CONCLUSIONS OF LAW

"This cause having come on to be heard on plaintiffs' motion for a preliminary injunction, and defendants' motion to dismiss the action and for summary judgment, the Court hereby files its Findings of Fact and Conclusions of Law as follows:

THE COURT FINDS

"1. The plaintiffs are, and were during the times mentioned in the petition for injunction, the owners of the Nu-Basic Products Company, which manufactures and sells in interstate commerce a drug product known as Pso-Ridisal for external use for diseases of the skin.

"2. The said drug consists of a mineral oil emulsion, sulfanilamide, carbolic acid (phenol), and other ingredients, and has been introduced into interstate commerce under the names Sulfa-Seb and Sulfa-Ped, as well as under the name Pso-Ridisal.

"3. On January 21, 1942, a shipment of Pso-Ridisal was seized pursuant to a libel of information filed by the Government under the Federal Food, Drug and Cosmetic Act in the United States District Court for the Northern District of Illinois. The libel alleged that the drug was misbranded because its labeling was false and misleading. The plaintiffs herein appeared as claimants of the seized article, and by consent a decree of condemnation based on said misbranding was entered on April 12, 1944.

"4. On January 28, 1944, a shipment of Pso-Ridisal was seized pursuant to a libel of information filed under the said Act in the United States District Court for the Western District of Missouri. The libel alleged that the drug was misbranded because its labeling was false and misleading. The plaintiffs herein appeared as claimants of the seized article, said action was thereafter removed to the United States District Court for the Northern District of Illinois, and said article so seized was condemned by consent decree of condemnation based on said misbranding on April 26, 1944.

"5. On November 10, 1943, shipments of said drug bearing the names Sulfa-Seb and Sulfa-Ped were seized pursuant to a libel of information filed under the said Act in the United States District Court for the Western District of Missouri. The libel alleged that the drug was misbranded because its labeling was false and misleading and because its labeling failed to bear adequate warnings against unsafe dosage or methods of use in a manner and form necessary for the protection of users. After trial, the said Court, on April 3, 1944, entered a decree based on said false and misleading labeling condemning the labeling of said drug.

"6. After the entry of the decrees above mentioned, applications were made by plaintiffs herein to the courts in which said actions had been filed praying that the seized articles be delivered to them to be brought into compliance with the provisions of the Federal Food, Drug, and Cosmetic Act under the supervision of an officer or employee of the Food and Drug Administration, which applications were granted upon the execution of sufficient bond conditioned as required by law. Thereafter, the plaintiffs herein submitted to the Food and Drug Administration for approval a proposed form of labeling to accompany the seized articles, which form of labeling the Food and Drug Administration, after due consideration, did not approve.

"7. Thereafter, the plaintiffs herein continued distributing its product in interstate commerce under the name Pso-Ridisal accompanied by labeling differing in minor respects from that which had accompanied the said drug involved in the actions above mentioned.

"8. On or about June 13, 1941, the Federal Security Administrator delegated to the Commissioner of Food and Drugs authority to make determinations of probable cause under Section 304 (a) of the said Act (21 U. S. C. 334 (a)).

"9. On July 29, 1944, the Commissioner of Food and Drugs determined that he had probable cause to believe, and that he did believe, on the basis of facts found by employees and officials of the Food and Drug Administration, that the labeling of said drug Pso-Ridisal would be and was in a material respect misleading to the injury or damage of the purchaser or consumer. Thereafter, a number of seizures of said drug with such labeling

were made pursuant to libels of information filed in different district courts of the United States.

"10. The plaintiffs herein, from the filing of said libel actions last above mentioned until the argument on plaintiffs' motion for a preliminary injunction and defendants' motion to dismiss this action and for summary judgment, did not, pursuant to Section 304 (b) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 334 (b)), apply to the court of one jurisdiction wherein one of said libel actions had been brought for an order consolidating all of said libel actions for trial in a district selected by the plaintiffs herein where one of such libel actions was pending.

"11. One of said seizure actions last above mentioned was commenced by the Government in the United States District Court for the Western District of Missouri, entitled 'United States v. 1233 Bottles Pso-Ridisal'. The plaintiffs herein appeared as claimants in said action and by motion filed on or about September 8, 1944, sought to have said action dismissed on the ground that other seizure actions involving said drug and founded on the same or similar allegations of misbranding were already pending in other district courts of the United States. The said District Court denied said application on September 16, 1944.

"12. On or about September 8, 1944, the plaintiffs herein filed in the United States District Court for the Western District of Missouri an action entitled 'Fred B. Collier et al. v. The United States of America, Federal Food and Drug Administration', praying an injunction restraining the further seizure of shipments of said drug. Said action was dismissed by said District Court on plaintiffs' motion on September 9, 1944.

"13. On or about September 16, 1944, the plaintiffs herein filed an action in the United States District Court for the Northern District of Illinois, entitled 'Fred B. Collier et al. v. Paul V. McNutt, Federal Security Administrator', praying that the said Administrator be enjoined from instituting a new libel proceedings against said drug Pso-Ridisal and from harassing or interfering with the plaintiffs' business. Said action was dismissed on motion of the plaintiffs on or about September 29, 1944.

"14. On or about September 20, 1944, the plaintiffs herein filed a petition in the United States District Court for the District of Columbia against the defendants herein seeking to restrain and enjoin them from instituting new libel proceedings and from further seizures of the product Pso-Ridisal, and from harassing and interfering with plaintiffs' operation of their business and the business of their distributors and dealers and from instituting any action based upon the same alleged misbranding which was the subject matter of the proceedings already instituted against the plaintiffs' said product; and prayed that a preliminary injunction be granted.

"15. On or about October 16, 1944, the defendants herein moved to dismiss this action and for summary judgment on the grounds that the petition of plaintiffs herein failed to state facts which entitled plaintiffs to the relief sought therein, and that this Court did not have jurisdiction of the subject matter of this action.

THE COURT FILES THE FOLLOWING CONCLUSIONS OF LAW

"1. On or about June 13, 1941, the Federal Security Administrator, pursuant to the authority vested in him by law, delegated to the Commissioner of Food and Drugs, Federal Security Agency, authority to make determinations of probable cause contemplated by Section 304 (a) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 334 (a)).

"2. The institution of multiple libel for condemnation actions against plaintiffs' product Pso-Ridisal was authorized by law inasmuch as the Commissioner of Food and Drugs of the Federal Security Agency had determined, pursuant to said Section 304 (a) of said Act (21 U. S. C. 334 (a)), that he had probable cause to believe and that he did believe, from facts found by officers and employees of the Food and Drug Administration, that the labeling of said drug Pso-Ridisal would be and was in a material respect misleading to the injury or damage of the purchaser or consumer.

"3. The actions of defendants complained of by plaintiffs herein were not illegal, were not in excess of the authority vested in defendants by law, and did not constitute an abuse of lawful duty.

"4. The petition filed by plaintiffs herein does not disclose any cause of action against the defendants named therein since said defendants do not and are not authorized to institute libel for condemnation or other suits in any court of the United States, and there is no mandatory duty vested in United States Attorneys or the Department of Justice to institute libel for condemnation or other suits on referral by or recommendation of defendants.

"5. The plaintiffs herein have not established that they have suffered or will suffer any irreparable or legal injury by the institution of libel for condemnation actions under the Federal Food, Drug, and Cosmetic Act against their product Pso-Ridisal.

"6. Since the petition filed by plaintiffs herein sought to restrain defendants, officials of the Federal Government, from performing their statutory functions, the action instituted by plaintiffs herein was a suit against the United States which had not consented to be sued, and this Court does not have jurisdiction of the subject matter of this action.

"7. The petition filed by plaintiffs herein establishes no grounds for equitable relief and fails to state facts which entitle the plaintiffs to the relief sought by them.

"8. The motion made by plaintiffs herein for a preliminary injunction should be denied.

"9. The motion made by defendants herein to dismiss this action and for summary judgment should be granted.

"Let the foregoing Findings of Fact and Conclusions of Law be filed, and order and decree be entered accordingly."

DRUGS FOR VETERINARY USE*

2141. Misbranding of Federal Swine Compound. U. S. v. Joseph Borkovec (Federal Chemical Co.). Plea of not guilty. Tried to the court and jury. Verdict of guilty. Fine, \$500 and costs. (F. D. C. No. 17843. Sample Nos. 19227-H, 19228-H.)

INFORMATION FILED: April 12, 1946, Northern District of Illinois, against Joseph Borkovec, trading as the Federal Chemical Company, Willow Springs, Ill.

ALLEGED SHIPMENT: The product, together with a number of leaflets entitled "Information Blank" and a number of pamphlets entitled "Stop Hog Losses," was shipped from the State of Illinois into the State of Iowa. The product was shipped on or about March 27, 1945, and the leaflets and pamphlets were shipped on or about March 5, 1945.

LABEL, IN PART: "Federal Original Swine Compound An All Liquid Hog Medicine * * * Oats Medicine * * * Drinking Water Medicine * * * Jess W. Jones, Willow Springs, Illinois (Owner and Producer Since 1917) Formerly Federal Chemical Company, Omaha, Nebr."

NATURE OF CHARGE: *Oats Medicine and Drinking Water Medicine.* Misbranding, Section 502 (a), the label statements "An All Liquid Hog Medicine * * * A Tested Prescription * * * Treatment Consists of Two Different Medicines, Oats Medicine [or "Drinking Water Medicine"]," as well as certain statements in the leaflets and pamphlets which accompanied the articles were false and misleading since they represented and suggested that the articles when used in combination would be efficacious in maintaining hogs in good condition and in bringing back to normal condition hogs which were not in good condition; that the articles would be efficacious in the prevention and treatment of necro, "bull-nose" or snuffles, necrotic enteritis, scours and bloody scours, "flu," swine plague, pneumonia, typhoid and paratyphoid infections in hogs, mixed infections, and parasites and worms; that they would be efficacious in the treatment of sick hogs and would stop hog losses; that they would aid in the correction and prevention of swine diseases; that they would go directly to the source of the disease; and that they would assure hog health. The articles would not be efficacious for the purposes stated or implied.

DISPOSITION: On May 5, 1947, the defendant having entered a plea of not guilty, the case came on for trial before a jury and resulted in a verdict of guilty. On May 16, 1947, the court imposed a fine of \$250 on each of the 2 counts of the information.

* See also No. 2114.

2142. Misbranding of Singer's Earth Crust Minerals. U. S. v. E. Albert Singer (Chain of Lakes Duck Farm). Plea of nolo contendere. Fine, \$60. (F. D. C. No. 17773. Sample Nos. 8446-F, 59901-F, 23601-H.)

INFORMATION FILED: March 27, 1946, Northern District of Illinois, against E. Albert Singer, trading as Chain of Lakes Duck Farm, Barrington, Ill.

ALLEGED SHIPMENT: From the State of Illinois into the States of Wisconsin, Indiana, and Texas. The product was shipped on or about November 12, 1943, and February 18 and October 17, 1944, and was accompanied by a number of display placards which were shipped with the product, and by a number of circulars which were shipped on or about December 28, 1943, and during the early part of March 1944. The placards were entitled "Livestock and Poultry Raisers," and the circulars were entitled "Singer's Earth Crust Minerals" and "All Livestock, Fowl and Plant Life Must Have Minerals." The product was a mixture of dirt dug from the defendant's farm, mixed with calcium carbonate, salt, and rock phosphate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Phosphorus (P) not less than 10 Per Cent * * * Calcium (Ca) not less than 20 Per Cent" were false and misleading since 2 shipments of the article contained materially less than 10 percent of phosphorus and materially less than 20 percent of calcium. Further misbranding, Section 502 (a), the label statement "Keep Live Stock and Poultry Healthy" and certain statements appearing in the circulars and placards accompanying the article were false and misleading. These statements represented, suggested, and created the impression that the article would be effective in keeping livestock and poultry healthy; that it would prevent poor digestion, loss of appetite, run-down condition, and diseases in general; that it would be effective in removing any species of worms from the intestines of livestock and poultry; that it would lower mortality and prevent the disease condition of poultry known as range paralysis; and that use of the article would save feeding costs. The article would not be effective for the purposes stated.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: June 11, 1946. The defendant having entered a plea of nolo contendere, the court imposed a fine of \$10 on each of the 6 counts.

2143. Misbranding of Wormine. U. S. v. Dr. Fenton's Vigortone Co. Plea of guilty. Fine, \$200. (F. D. C. No. 14268. Sample No. 40661-F.)

INFORMATION FILED: August 22, 1945, Northern District of Iowa, against Dr. Fenton's Vigortone Co., a partnership, Cedar Rapids, Iowa.

ALLEGED SHIPMENT: On or about August 25, 1943, from the State of Iowa into the State of Minnesota.

PRODUCT: Analysis of a sample of the *Wormine* showed that it consisted essentially of linseed meal, not over 1.9 percent of santonin, areca nut, and other plant materials, including tobacco (nicotine, 0.15 per cent), kamala, and anise.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label were false and misleading since they represented, suggested, and implied that the article, when used alone or in combination with other products, i. e., "Health Pep" and "Moregg," and administered in compliance with specific directions, would be efficacious in the cure, mitigation, treatment, prevention, and removal of worms in poultry, and would increase the health, vigor, and tone of the system; and that, after the *Wormine* or combination of *Wormine* and other products had cured worm conditions and had removed worms from poultry, the continued use of "Health Pep" and "Moregg" would prevent worms in poultry and would result in the production of more eggs. The *Wormine*, and other products, when used as so recommended, would not accomplish the results claimed.

The information consisted of 3 counts. The first count charged violation under the provisions of the law applicable to drugs, as reported herein. The remaining counts charged adulteration of products known as "Moregg" and "Dr. Fenton's Vigortone No. 5½" under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: November 6, 1946. A plea of guilty having been entered, the court imposed a fine of \$200, plus costs, on each count of the information.

2144. Misbranding of Acidox and Germozone. U. S. v. 272 Bottles, etc., and a number of catalogs (and 10 seizure actions against other lots of the same products). (F. D. C. Nos. 15963, 15972, 15983, 16006, 16032, 16184, 16193, 16199. Sample Nos. 14661-H, 14662-H, 17620-H, 17621-H, 18578-H to 18581-H, incl., 18734-H to 18739-H, incl., 18993-H to 18997-H, incl., 19211-H to 19215-H, incl., 19219-H to 19226-H, incl., 20361-H to 20364-H, incl.)

LIBELS FILED: Between May 1 and June 5, 1945, District of Kansas, District of Minnesota, Eastern District of Michigan, Western District of Wisconsin, and Southern District of Iowa.

ALLEGED SHIPMENT: Between the approximate dates of January 4, 1944, and April 16, 1945, from Omaha, Nebr., by the George H. Lee Co.

PRODUCT: 1,182 bottles of *Acidox* and 1,384 bottles of *Germozone* at Chanute, Kans.; Lyle, Richmond, and Waseca, Minn.; Detroit, Mich.; What Cheer and Thornburg, Iowa; and Madison, Wis. The bottles of the products consisted of 4-ounce-, 12-ounce-, 1-quart-, $\frac{1}{2}$ -gallon-, and 1-gallon-sizes. The products were accompanied by catalogs entitled "The Lee Way Poultry Book 1943" and "The Lee Way Poultry Book 1944" and a window poster entitled "Give Your Chicks This Triple Protection."

Analyses of samples showed that the *Acidox* consisted of 9.7 percent of acetic acid, 12 percent of sodium chloride, 6.1 percent of sodium bisulfate, 2.7 percent of zinc chloride, 1.3 percent of pyridine, and approximately 68.2 percent of water; and that the *Germozone* consisted of 1.4 percent of potassium permanganate, 1.3 percent of potassium chlorate, 4.2 percent of aluminum sulfate, 24.5 percent of sodium chloride, 0.6 percent of potassium chloride, and approximately 68 percent of water.

NATURE OF CHARGE: *Acidox*. Misbranding, Section 502 (a), certain statements and designs in the labeling of the article were false and misleading since they represented and suggested that the article when used as directed would be an effective treatment and preventive of coccidiosis of poultry and rabbits, and that it would be effective to control protozoan parasites and parasitic worms. The article when used as directed would not be effective for such purposes.

Germozone. Misbranding, Section 502 (a), certain statements and designs in the labeling of the article were false and misleading since they represented and suggested that the article, by reason of its germicidal or bactericidal properties, would be effective when used as directed, in the drinking water to successfully combat disease conditions of poultry and livestock caused by germs; that it would be effective to prevent transmittal of such diseases; that it would be effective when used as directed in the treatment and prevention of coccidiosis, diarrhea, bowel trouble, and other serious disease conditions of poultry; that it would be effective in the treatment of scours, necrotic enteritis, and other disease conditions of calves, pigs, and other livestock; and that it would be effective by reason of its astringent action, to combat diseases of the digestive tract of fowls and other animals. The article would not be effective for such purposes.

DISPOSITION: The George H. Lee Co., claimant, having petitioned for consolidation of the cases, an order was entered by the Court for the Eastern District of Michigan, directing that the cases other than the Michigan case be removed and consolidated for trial with the Michigan case. On October 28, 1946, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered destroyed.

2145. Misbranding of Korum. U. S. v. 156 Bottles * * *. (F. D. C. No. 22287. Sample No. 41130-H.)

LIBEL FILED: February 17, 1947, Southern District of Illinois.

ALLEGED SHIPMENT: On or about February 2, 1945, and January 2, 1947, by the I. D. Russell Laboratories, from Kansas City, Mo.

PRODUCT: 24 8-fluid-ounce bottles, 107 16-fluid-ounce bottles, 12 32-fluid ounce bottles, and 13 1-gallon bottles of *Korum* at Carrollton, Ill. Analysis of the product showed that it consisted essentially of water, with small amounts of sodium chlorate, potassium dichromate, saltpeter, and epsom salt.

LABEL, IN PART: "Korum for Poultry."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements appearing in the label were false and misleading since they represented and suggested that the article would be effective as a mild astringent for chicks, pullets, layers and breeders, turkeys, and poult, and in the prevention and treatment

of disease conditions of poultry. The article would not be effective for such purposes.

DISPOSITION: April 21, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2146. Misbranding of N-D-R Tablets and Choloid Tablets. U. S. v. 59 Bottles, etc. (F. D. C. No. 19733. Sample Nos. 19897-H, 19898-H.)

LIBEL FILED: April 29, 1946, Northern District of Iowa.

ALLEGED SHIPMENT: On or about November 15, 1945, by the Northwest Poultry Supplies Co., from Sioux Falls, S. Dak.

PRODUCT: 59 bottles of *N-D-R Tablets* and 38 bottles of *Choloid Tablets* at Spencer, Iowa. Analysis showed that the *N-D-R Tablets* consisted essentially of potassium dichromate, 0.82 grain per tablet, and iodine, 0.02 grain per tablet, with small amounts of creosote and guaiacol, and that the *Choloid Tablets* consisted essentially of copper sulfate, citrate arsenite, zinc, calcium, and sodium sulfocarbonates.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain label statements were false and misleading. These statements represented and suggested that the *N-D-R Tablets* would be effective in the treatment of colds, röup, bronchitis, nasal discharges, swollen eyes, and cankerous throats of poultry; and that the *Choloid Tablets* would be effective for cholera and fowl typhoid of poultry, would be effective as a preventive and to check all bowel troubles of poultry, would be effective in the treatment of severe intestinal disorders, including cholera and fowl typhoid, and would be effective as a stimulant to the laying flocks. The articles would not be effective for the purposes claimed.

DISPOSITION: May 29, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

2147. Misbranding of Swinade and Diarex. U. S. v. 314 Cans, etc. (F. D. C. No. 19723. Sample Nos. 19645-H, 19646-H.)

LIBEL FILED: May 3, 1946, District of Minnesota.

ALLEGED SHIPMENT: On or about July 13, 1944, by the Central Laboratories, from Bensenville, Ill.

PRODUCT: 238 1-pound cans and 78 5-pound cans of *Swinade* and 178 7-ounce cartons of *Diarex* at Mankato, Minn. Analysis showed that the *Swinade* consisted essentially of sulfur, iron sulfate, mandrake, strychnine-bearing material, corn meal, hydrated lime, and a magnesium compound, and that the *Diarex* consisted essentially of bismuth subnitrate and subcarbonate, phenyl salicylate, tannic acid, sodium bicarbonate, and calcium and magnesium carbonates.

NATURE OF CHARGE: *Swinade*. Misbranding, Section 502 (a), the designation "Swinade" and certain statements appearing on the label represented and suggested that the article would be an aid for swine, would be effective to help eliminate intestinal parasites and large round worms in swine, and would be effective to eliminate intestinal parasites in swine by repeating the treatment in 7 days when a herd was heavily infected with worms. The article would not be an aid for swine, and would not be effective for the purposes stated and implied.

Diarex. Misbranding, Section 502 (a), the designation "Diarex" and certain statements appearing on the label of the article were false and misleading since they represented and suggested that the article would be effective in the prevention and treatment of scours and diarrhea in animals. The article would not be effective for such purposes.

DISPOSITION: July 3, 1946. No claimant having appeared, judgment was entered ordering that the product be destroyed.

DRUG ACTIONABLE BECAUSE OF OMISSION OF, OR UNSATISFACTORY, INGREDIENTS STATEMENTS*

2148. Misbranding of Ramol. U. S. v. 1 Drum * * * (and 1 other seizure action). (F. D. C. Nos. 21401, 21827. Sample Nos. 52766-H, 60869-H.)

LIBELS FILED: November 6 and December 10, 1946, Northern District of Ohio.

*See also Nos. 2105, 2134.

ALLEGED SHIPMENT: On or about September 20 and October 1, 1946, by B. Ostroff, from Pittsburgh, Pa.

PRODUCT: *Ramol*. 1 drum at Salem, Ohio, and 1 drum at Cleveland, Ohio. Each drum contained 30 gallons. Examination showed that the product was mineral oil, U. S. P.

LABEL, IN PART: "Ramol No. 350 U. S. P."

NATURE OF CHARGE: Misbranding, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, i. e., mineral oil.

DISPOSITION: December 16, 1946, and January 9, 1947. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ACCURATE STATEMENTS OF THE QUANTITY OF THE CONTENTS

2149. Misbranding of Compound Flaxseed and Wild Cherry Cough Syrup and White Pine and Tar Compound. U. S. v. 10 Cases, etc. (F. D. C. No. 22299. Sample Nos. 57664-H, 57665-H, 57670-H, 57674-H, 57687-H, 57688-H.)

LABEL FILED: February 21, 1947, District of Maine.

ALLEGED SHIPMENT: On or about November 7, 1946, by the Boston Drug and Chemical Co., from Boston, Mass.

PRODUCT: *Cough syrup*. 10 cases containing 480 bottles and 15 cases containing 864 bottles at Portland, Maine.

LABEL, IN PART: "Compound Flaxseed and Wild Cherry Cough Syrup [or "White Pine and Tar Compound"] Contents 3 Fluid Ounces The Caron Company Distributor Portland, Maine."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the labels of the articles failed to bear accurate statements of the quantity of the contents, since both products were short-volume.

DISPOSITION: April 15, 1947. The Boston Drug and Chemical Co., Brookline, Mass., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered released under bond, conditioned that they be relabeled or that the containers be refilled so as to comply with the requirements of the law, under the supervision of the Federal Security Agency.

2150. Misbranding of Lucille Laner's Pressing Oil and Lucille Laner's Tar Treatment. U. S. v. 247 Tins * * *. (F. D. C. No. 19445. Sample Nos. 12759-H, 12760-H, 56768-H, 56769-H.)

LABEL FILED: March 18, 1946, District of Massachusetts.

ALLEGED SHIPMENT: On or about December 1, 1945, by Madam Lillian, from New York, N. Y.

PRODUCT: 247 2-ounce tins of *Lucille Laner's Pressing Oil* and *Lucille Laner's Tar Treatment* at Roxbury, Mass. The product was shipped unlabeled. The tins contained approximately 1½ ounces, and were labeled "2 Oz." after receipt by the consignee.

LABEL, IN PART: "Lucille Laner's Pressing Oil," or "Lucille Laner's Tar Treatment."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), (when shipped) the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

The article was alleged also to be misbranded under the provisions of the law applicable to cosmetics, as reported in notices of judgment on cosmetics, No. 146.

DISPOSITION: April 29, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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¹ (2121) Prosecution contested. Contains opinion of the court.²(2105, 2141) Prosecution contested.³(2140) Injunction contested. Contains findings of fact and conclusions of law.

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¹ (2121) Prosecution contested. Contains opinion of the court.² (2140) Injunction contested. Contains findings of fact and conclusions of law.

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3. Notice of proposed rule making;

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Washington, Wednesday, February 5, 1947

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FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2151-2200

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

OSCAR R. EWING, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., December 22, 1947.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2151. Misbranding of Yuk-Air Compound. U. S. v. Albert Hassman. Motion to dismiss indictment denied. Plea of guilty. Fine, \$800 and costs. (F. D. C. No. 14285. Sample Nos. 49064-F, 50177-F, 59721-F.)

INDICTMENT RETURNED: February 13, 1945, Northern District of Ohio, against Albert Hassman, president of Universal Drug Products, Inc., Cleveland, Ohio.

ALLEGED SHIPMENT: Between the approximate dates of February 5 and 18, 1944, from the State of Ohio into the States of Michigan, Indiana, and West Virginia.

PRODUCT: Analysis disclosed that a portion of the *Yuk-Air Compound* was a colorless liquid consisting essentially of oil of turpentine and that the remainder of the product was a yellow liquid, some consisting of oil of eucalyptus and some consisting essentially of oil of eucalyptus and oil of turpentine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article, in accompanying circulars entitled "Yuk-Air Daily, Vol. 1, Universal Edition, 1944," and in accompanying placards were false and misleading since they represented and suggested that the article would be safe for use on every part of the body; that it would be appropriate for use generally as

* For new drug shipped without effective application, see No. 2151; failure to bear a label containing the place of business of the manufacturer, packer, or distributor, No. 2200; inconspicuousness of required label information, No. 2184; cosmetics, subject to the drug provisions of the Act, Nos. 2167, 2184.

a massaging and rubbing oil and could be used and rubbed on the body freely without fear of irritation of any kind; that it would be an efficacious treatment for stiff joints; that it would be efficacious in the cure, mitigation, treatment, and prevention of colds, influenza, coughs, asthma, sinus, and catarrhal conditions; that it would be efficacious in the mitigation and treatment of disease and disease conditions accompanied by fever; and that it would be efficacious in dissipating fever and restoring normal body temperature. The article would not be safe for use on every part of the body; it would not be appropriate for use generally as a massaging and rubbing oil, and it might cause irritation to the skin when used as directed; and it would not be efficacious for the purposes represented.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage suggested in the labeling, "Eucalyptus Oil * * * Used in * * * Ear Oil" and "It may be used safely on any part of the body," since when used in the ears the article would cause injury.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, against unsafe methods and duration of application, in such manner and form, as are necessary for the protection of users, since its labeling failed to bear warnings against allowing the article to get into the eyes and ears or onto the mucous membrane, and against continued use of the article if excessive irritation should develop, since the article might be harmful to the eyes, ears, mucous membrane, and irritated skin.

Further misbranding, Section 505, the article was a new drug within the meaning of the law in that it was not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions recommended and suggested in their labeling; and application filed, pursuant to the law, was not effective with respect to the article.

The indictment alleged also that another product, *Sol-A-Min*, was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: March 31, 1947. The defendant's motion to dismiss the indictment having been denied, a plea of guilty was entered and the court imposed a fine of \$1,000, plus costs.

2152. Adulteration and misbranding of procaine hydrochloride solution. U. S. v. A. Pfingst, a partnership, and Ernest Pfingst. Pleas of guilty. Fine of \$500 against both defendants jointly and severally. (F. D. C. No. 14300. Sample Nos. 35041-F, 50281-F.)

INFORMATION FILED: March 7, 1947, Southern District of New York, against A. Pfingst, a partnership, and Ernest Pfingst, New York, N. Y.

ALLEGED SHIPMENT: Between the approximate dates of March 7 and 20, 1944, from the State of New York into the States of Georgia and Pennsylvania.

LABEL, IN PART: "Procaine Hydrochloride Solution 2% with Epinephrin (Pfingst)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, since the appropriate use for the article required that it be a sterile product, whereas it was nonsterile and contaminated with living micro-organisms.

Misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage suggested in the labeling, due to the presence of living micro-organisms.

DISPOSITION: May 1, 1947. Pleas of guilty having been entered, the court imposed a fine of \$500 against both defendants jointly and severally.

2153. Misbranding of first aid kits and contents. U. S. v. 15,000, etc. (F. D. C. Nos. 20530, 20531. Sample Nos. 63802-H to 63804-H, incl.)

LIBELS FILED: July 18, 1946, Southern District of New York.

ALLEGED SHIPMENT: Between the approximate dates of May 17 and August 13, 1945, by Burke Drug Supply, from Dayton, Ohio.

PRODUCT: 15,000 complete *first aid kits with contents* and 5,500 incomplete *first aid kits* at New York, N. Y.; also 5,500 vials of *Amphetamine sulfate tablets*, 5,500 vials of *wound tablets*, and 500 vials of *atabrine tablets*, all of which had

been removed from the incomplete kits. These kits contained a bottle of *mild tincture of iodine*. The kits were intended to be incorporated into certain emergency equipment for utilization by the Army.

LABEL, IN PART: (First aid kits) "First Aid Instructions Vest, Emergency, Sustenance Type C-1."

NATURE OF CHARGE: *Amphetamine sulfate tablets*, misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, as follows: (case and vial label) "Directions: Take one tablet if sleepy or two tablets if extremely fatigued. Repeat this dose in six hours if necessary but do not take more than * * *" (vial label) " * * * six tablets in any one week" and (case label) " * * * four tablets in any 12 hour period."

Wound tablets, misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling, as follows: (vial label) "Use—When Hit: Take all tablets. Drink lots of water" and (case label) "Wounds—Take internally by mouth, followed by a large amount of water, 8 Sulfadiazine Tablets."

Atabrine tablets, misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since the following directions appearing in the labeling were not adequate directions for use in the prevention or treatment of malaria: (vial label) "Use: For prevention of Symptoms of Malaria. Take first dose (1 tablet) in the morning and second dose (1 tablet) in the evening after meals on two days of each week. Skip 2 or 3 days between days of taking Atabrine. Start to take Atabrine on first day you are in malarial area and continue to take it as long as you are in a malarial area" and (case label) "Malaria (Chills and Fever) (Prevention) * * * ." [Directions similar to those on vial.]

Mild tincture of iodine, misbranding, Section 502 (a), the statement "50% isopropyl alcohol" on the label was false and misleading since the article contained no isopropyl alcohol.

DISPOSITION: On November 20, 1946, the Ever Ready First Aid Company, New York, N. Y., claimant for the products, with the exception of 2,500 complete first aid kits, having admitted the allegations of the libel, judgment of condemnation was entered and it was ordered that the products be released under bond to be relabeled and repackaged as specified in the order, so as to comply with the law, under the supervision of the Food and Drug Administration. On November 6, 1946, the claim for the 2,500 remaining kits having been withdrawn, judgment of condemnation was entered and the product was ordered delivered to the Department of Hospitals of the City of New York.

2154. Misbranding of first aid kits. U. S. v. 13,500 * * *. (F. D. C. No. 20586. Sample No. 63805-H.)

LIBEL FILED: August 9, 1946, Southern District of New York.

ALLEGED SHIPMENT: Between the approximate dates of May 22 and August 14, 1945, by Burke Drug Supply, from Dayton, Ohio.

PRODUCT: 13,500 complete *first aid kits* at New York, N. Y. These kits were intended for use as part of emergency equipment for the Army. When the war ended, the contract was terminated and the kits were sold separately as surplus to a private dealer. Each of the kits contained, among other items, vials of tablets designated as "Amphetamine Sulfate— 5 MG.," "Atabrine Tablets," and "Wound Tablets," and a small bottle of a solution designated as "Mild Tincture Iodine 2 cc. U.S.P. * * * 50% Isopropyl Alcohol." The *wound tablets* contained sulfadiazine. The *mild tincture iodine* contained no isopropyl alcohol.

LABEL, IN PART: "First Aid Instructions Vest, Emergency, Sustenance Type C-1."

NATURE OF CHARGE: *Mild tincture iodine*, misbranding, Section 502 (a), the label statement "50% Isopropyl Alcohol" was false and misleading since the article contained no isopropyl alcohol.

Atabrine tablets, misbranding, Section 502 (f) (1), the label failed to bear adequate directions for use since the following directions appearing in the labeling were not adequate directions for use in the prevention or treatment of malaria: (Vial label) "Use: for prevention of Symptoms of Malaria. Take

first dose (1 tablet) in the morning and second dose (1 tablet) in the evening after meals on 2 days of each week. Skip 2 or 3 days between days of taking Atabrine. Start to take Atabrine on first day you are in a malarial area and continue to take it as long as you are in a malarial area" and (case label) "Malaria (chills and fever) (prevention) * * * ." [Directions substantially the same as those on vial.]

Amphetamine sulfate tablets, misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, as follows: (Vial label) "Directions: Take 1 tablet if sleepy or 2 tablets if extremely fatigued. Repeat this dose in 6 hours if necessary, but do not take more than 6 tablets in any 1 week" and (kit label) [Directions substantially the same as those on vial.]

Wound tablets, misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling, as follows: (Vial label) "Use—when hit: take all tablets. Drink lots of water * * *" and (case label) "Wounds—take internally by mouth, followed by a large amount of water, 8 Sulfadiazine tablets."

DISPOSITION: November 14, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Department of Hospitals of the City of New York, for use in the medical care and treatment of sick persons, conditioned that the recipient remove the articles from the kits and containers and relabel them in compliance with the law, or that the recipient itself distribute and administer the articles to patients, under the supervision of proper medical authorities.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2155. Misbranding of Tru-Lax Tablets, Natural B Complex Tablets, Nurex Tablets, Vitamin Minerals Tablets, Sleen Tablets, Sleen Pellets, and Sleen Herb Tea. U. S. v. 14 Bottles, etc. (F. D. C. No. 14661. Sample Nos. 81582-F to 81585-F, incl., 81587-F to 81589-F, incl.)

LABEL FILED: On or about December 26, 1944, Western District of Missouri.

ALLEGED SHIPMENT: On or about October 23 and 25, 1944, by the Pavo Co., from Minneapolis, Minn.

PRODUCT: 14 bottles of *Tru-Lax Tablets*, 9 bottles of *Natural B Complex Tablets*, 21 bottles of *Nurex Tablets*, 21 bottles of *Vitamin Minerals Tablets*, 34 bottles of *Sleen tablets*, 22 bottles of *Sleen Pellets*, and 21 bottles of *Sleen Herb Tea* at Kansas City, Mo., together with a number of circulars entitled "Slenderize by the 'Sleen' System" and "Are You Below Par?"

The *Sleen Herb Tea* was in 2½-ounce-size bottles, and the other products were contained in 65-, 75-, 80-, 85-, 150-, 185-, 250-, 270-, and 285-tablet-size bottles. Examination showed that the *Tru-Lax Tablets* contained laxative drugs, such as cascara sagrada, aloe, and senna, flavored with anise, peppermint, and juniper berries; that the *Natural B Complex Tablets* contained vitamin B₁, riboflavin, and niacin; that the *Nurex Tablets* contained vitamin B₁, calcium, magnesium, iron, sodium, and potassium; that the *Vitamin Minerals Tablets* contained calcium, phosphorus, and iron compounds, vitamin C and organic matter, and traces of iodides and copper; that the *Sleen Tablets* contained compounds of calcium, phosphorus, iron, and iodine, and green plant matter; that the *Sleen Pellets* consisted of pink compressed tablets such as would be made from milk sugar and phytolacca berry juice; and that the *Sleen Herb Tea* consisted essentially of a large proportion of senna leaves with other plant material, including fennel seed, anise, peppermint and bark, and stem and leaf fragments.

NATURE OF CHARGE: *Tru-Lax Tablets*, misbranding, Section 502 (a), certain statements in the labeling were false and misleading since they represented and suggested that the article would be efficacious in the treatment of headaches, constipation, auto-intoxication, nervousness, tiredness, discharge from the ears, nose, throat, navel, and rectum, and many other common ailments; and that the article would cleanse the alimentary canal, regulate the flow of bile

* See also Nos. 2151, 2153, 2154.

from the liver, cleanse and strengthen the kidneys, purify the blood stream, and tone up the entire system. The article would not fulfill the promises of benefit stated and implied. Further misbranding, Section 502 (f) (2), the labeling failed to bear adequate warning against unsafe duration of administration, since the warning "Laxatives should not be taken regularly over an extended period of time as they may become a habit" had been made inadequate by the direction "Directions for best results. For the first 10 to 15 days on retiring take one or two tablets with a full glass of water; then as needed."

Natural B Complex Tablets, misbranding, Section 502 (a), certain statements in the labeling were false and misleading since the article would not fulfill the promises of benefit stated and implied. The statements represented and implied that the article would be of value to persons who were below par and always tired, sleepy, and listless; and that it would make one feel like a new person and enable one to live his life in a way to enjoy it.

Nurex Tablets, misbranding, Section 502 (a), certain statements in the labeling were false and misleading since they represented and suggested that the article was of nutritional and therapeutic value because of the presence of sodium, potassium, and magnesium; that it would be of value to ones who were nervous, irritable, despondent, blue, and unable to sleep nights; and that it would relax taut nerves. The article was of no nutritional or therapeutic value by reason of the minerals mentioned, and it would not be effective to fulfill the promises of benefit stated and implied.

Vitamin Minerals Tablets, misbranding, Section 502 (a), certain statements in the labeling were false and misleading since they represented and suggested that the article would enable persons to keep healthy, young, and beautiful, and to keep their skin, hair, and nails in youthful condition. The article would not fulfill the promises of benefit stated and implied.

Sleen Tablets, *Sleen Pellets*, and *Sleen Herb Tea*, misbranding, Section 502 (a), certain statements in the labeling were false and misleading since they represented and suggested that the articles would be effective to reduce the weight of the user, to provide important amounts of essential food elements, to supply nutritional balance, to build physically while getting rid of excess weight, and to help in gradually changing body processes to a normal state. The article would not be effective for such purposes.

The *Natural B Complex Tablets*, *Nurex Tablets*, and *Vitamin Minerals Tablets* were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: October 18, 1945. Jack G. Pavo, trading as the Pavo Co., having appeared as claimant and having filed an answer denying that the products were misbranded, and the court having found that the articles were misbranded within the meaning of the law, judgment of condemnation was entered. The products were ordered released under bond to be brought into compliance with the law by relabeling or destruction, as the circumstances might require, under the supervision of the Food and Drug Administration.

2156. Misbranding of West's preparations. U. S. v. 56 Bottles * * *. (F. D. C. No. 22747. Sample Nos. 90326-H to 90336-H, incl.)

LIBLE FILED: March 28, 1947, District of Columbia.

ALLEGED SHIPMENT: On or about March 24, 1947, and on prior dates by Mineralized Foods, Inc., from Baltimore, Md.

PRODUCT: 62 bottles of *West's Imported Sea Vegetable Tablets*, 42 bottles of *West's Sea Vegecene (Powder)*, 38 bottles of *Ferrolene Tablets*, 42 bottles of *West's Sodeom Tablets*, 20 bottles of *West's Sodeom (Vitamized Sodeom Tablets)*, 45 bottles of *West-Aid Tablets*, 32 bottles of *West's Kalseom Tablets*, 16 bottles of *West's Sea-Vo-Kra Tablets*, 16 bottles of *West's Imported Sea Vegetation Tablets (Vitaminized with added Vitamin A)*, 35 bottles of *F Y A Tablets*, and 46 bottles of *West's Pro-Pi-Ya Tablets*.

The products were located at Washington, D. C. The *West's Sea Vegecene (Powder)* was contained in 5- and 8-ounce-size bottles, and the other products were contained in 100-, 240-, 400-, or 500-tablet-size bottles. The products consisted preponderantly of sea vegetation, such as kelp, seaweed, etc., with added vitamins in some instances.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in arthritis, neuritis, angina

pectoris, apoplexy, heart diseases, cerebral hemorrhages, arteriosclerosis, and high and low blood pressure; in providing resistance to infection and epidemics; in preventing a variety of maladies from diseased tonsils to mysterious nervous disorders, pain in the bones and bone marrow, brain and nerve disturbances, lassitude, nausea, vomiting, headaches, sleeplessness, loss of appetite, and damage to teeth; in lengthening life; in preventing cancer and tooth decay; in preventing or curing an alarming number of dreaded diseases, rickets, neuritis, scurvy, softening of the bones, hairlessness, paralysis, bone and joint disease, malnutrition, leg weakness, roup, stiff neck, beriberi, black tongue, ulcerated gums, falling teeth, sores, and dropsy; in changing a hopeless physical wreck to an individual of buoyant, glowing health; in improving the health of people suffering from a wide variety of nutritional diseases; in preventing and curing arthritis, rheumatism, neuritis, high blood pressure, low blood pressure, heart condition, nervousness, frequent colds, kidney condition, sleeplessness, constipation, migraine headaches, skin conditions, poor eyesight, hay fever, asthma, sinus infection, continual tiredness, underweight, overweight, stomach and intestinal ulcers, anemia, general weakness, diabetes, painful and irregular menstruation, dropsy, swollen limbs, gall bladder conditions, supersensitivity, brittle fingernails, stiff joints, poor memory, poor circulation, mucous condition, low energy, glandular disturbances, varicose veins, epilepsy, palsy, cataracts, catarrhal conditions, tooth malformation, excessive acid, stomach trouble, and other degenerative diseases; in helping nutritionally to relieve, ease, and lessen excessive acid pains in arthritis; in increasing resistance to the causative factors of disease; and in preventing flu, such as was prevalent in the 1918 epidemic. The diseases, symptoms, and conditions mentioned were those for which the articles were prescribed, recommended, and suggested in advertising sponsored by and on behalf of their manufacturer, packer, and distributor.

DISPOSITION: June 28, 1947. Default decree of condemnation and destruction.

2157. Misbranding of diathermy machines. U. S. v. 2 * * *. (F. D. C. No. 21905. Sample No. 42175-H.)

LIBEL FILED: November 27, 1946, District of Columbia.

ALLEGED SHIPMENT: On or about November 14, 1946, by the David Bogen Co., Inc., from New York, N. Y.

PRODUCT: 2 *diathermy machines* at Washington, D. C. The machines were invoiced as "5-A Diathermy Machines," and they were offered to the general public for such conditions as rheumatism, arthritis, neuritis, bursitis, sciatica, lumbago, sinus congestions, and common colds.

LABEL, IN PART: "Model No. 5-A * * * Turn Past 3 * * * Then Set for Time."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the machines failed to bear adequate directions for use.

DISPOSITION: July 29, 1947. The Sun Radio Service and Supply Corporation, Washington, D. C., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency.

DRUG ACTIONABLE BECAUSE OF THE PRESENCE OF A NONCERTIFIED COAL-TAR COLOR

2158. Adulteration and misbranding of Kao Drops. U. S. v. 383 Bottles * * *. (F. D. C. No. 22523. Sample No. 40482-H.)

LIBEL FILED: February 14, 1947, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about November 6 and 8, 1946, by the Kao Co., from Texarkana, Ark.

PRODUCT: 383 1-fluid-ounce bottles of *Kao Drops* at Advance, Mo. Examination showed that the product consisted essentially of ether, with small proportions of salicylic acid and oil of peppermint, and that it was colored with amino-azo-ortho-toluene (Colour Index No. 17).

NATURE OF CHARGE: Adulteration, Section 501 (a) (4), the article contained, for purposes of coloring only, a coal-tar color which had not been listed as

harmless and suitable for use in drugs in accordance with regulations and was other than one from a batch that had been certified.

Misbranding, Section 502 (a), the label statements "For the relief of rheumatic pains * * * one drop at a time upon the pain area until the desired relief is effected" were false and misleading since the article would not be effective for the relief of rheumatic pains.

DISPOSITION: April 14, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2159. Adulteration and misbranding of Dwarfies 10-Vitamin Tablets. U. S. v. Dwarfies Corporation and James John Oberdin. Pleas of guilty. Each defendant fined \$200 and costs. (F. D. C. No. 17831. Sample No. 26455-H.)

INFORMATION FILED: October 1, 1946, Southern District of Iowa, against the Dwarfies Corporation, Council Bluffs, Iowa, and James John Oberdin, secretary and treasurer.

ALLEGED SHIPMENT: On or about March 14, 1945, from the State of Iowa into the State of Colorado. The article was accompanied by a leaflet entitled "Vitamin Chart," a letter entitled "Dear Friend," and a circular entitled "Thousands of Folks use Dwarfies 10-Vitamin Tablets Daily . . . and live a more healthy life because of it." The Vitamin Chart was shipped with the drug, and the other material was delivered to the consignee on or about March 19, 1945.

PRODUCT: Examination of a sample showed that it contained 2,760 U. S. P. units of vitamin A per tablet.

LABEL, IN PART: "Dwarfies 10 Vitamins All-In-One Daily Tablet Each tablet contains: Vitamin A, D, B₁, B₆, C, E, Niacin, Calcium Pantothenate, Paraminobenzoic Acid * * * Each tablet contains the following proportion of established minimum requirements: A, 125% * * * A . . . 5000 U. S. P. Units."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess since it contained less than 5,000 U. S. P. units of vitamin A per tablet.

Misbranding, Section 502 (a), the label statements "Each Tablet Contains * * * A 5000 USP Units" and "Each Tablet Contains the Following Proportion of Established minimum Requirements * * * A, 125%" were false and misleading. Certain statements in the accompanying letter, circular, and leaflet were misleading. These statements represented and suggested that the following conditions are frequently caused by lack of the vitamin substances contained in the article, and that the reader might reasonably expect correction and relief from those conditions by use of a product containing such substances: Abnormal vitality of mucous membrane or epithelial cells, low resistance to infection, abnormal functioning of the visual purple (bad eyesight), abnormal glandular function, abnormal lactation, improper formation of bone and teeth, poor appetite, poor utilization of carbohydrates, abnormal intestinal function, improper nerve function and cell respiration, abnormal nerve tissues, unclear, dull eyes, improper healing of wounds and repair tissue, faulty control of collagen formation, abnormalities of the vascular system, poor health, abnormal function of the gastrointestinal tract, poor utilization of unsaturated fatty acids, lack of virility, unsound muscle functioning and general well-being, poor intestinal motility, lack of growth, loss of natural hair color, abnormal blood calcium level, lack of vigor and well-being, loss of characteristics of youth, and a shortened life span. The stated conditions commonly and usually result from causes other than lack of the vitamin substances contained in the article, and the article would not ordinarily correct and relieve such conditions.

Further misbranding, Section 502 (a), certain statements in the labeling were misleading since they represented and suggested that the following conditions are frequently caused by lack of the vitamin substances contained in

*See also No. 2152.

the article, and that the reader might reasonably expect correction and relief from such conditions by use of a product containing such substances: Lack of body strength, sleeplessness, body aches, neuritis, indigestion, poor body function, a run-down, tired, and worn-out feeling, arthritis, back ailment, poor appetite, heart disease, disability of the legs, retarded growth, diarrhea, intestinal disorders, poor appetite, poor teeth and gums, lack of vigor, a dry skin, night blindness, poor resistance to infection, xerophthalmia (eye disease), hyperkeratosis of the skin, weakness, sterility, loss of weight, atrophy of glands, calculi (stones) in kidneys and bladder, nerve degeneration, infections entering through epithelia, eyes, tear ducts, tongue, alimentary tract, ear canal, sinuses, bladder, and kidneys, colitis, weakness (fatigue), slow heartbeat, poor appetite, retarded growth, cardiovascular disturbances, poor assimilation, nervousness, decreased peristalsis, impaired reproductive functioning, heaviness of legs, burning feet, pain in legs, paresthesia of toes, calf muscle cramps, anorexia, paralysis, loss of weight, atrophy of glands, atrophy of musculature, gastric atony, convulsions, enlarged heart, serious effusions and colitis, lesions of the lips, cracks at the angles of the mouth and other facial lesions, abnormal changes in the eyes which result in failing vision, digestive disturbances, lack of vigor, poor lactation, impaired growth, photophobia (evidenced by easy watering of the eyes in sun-glare), small blood vessels advance into the corneal area of the eyes, clouding the vision, itching, burning, a sensation of roughness of the eyes, weakness, atrophy of intestines, atony, loss of body weight, cataract (in eyes), keratitis, "sharkskin," glossitis, cheilosis, dermatitis (seborrheic), breakdown of central nervous system, anemia, hemorrhage, pyorrhea, defective teeth, tender joints, poor bone knitting, headache, poor resistance to infection, retarded growth, weakened blood capillaries, weakness, restlessness, tendency to bruise easily, as evidenced by dark discolor of skin, anemia, swollen joints, swollen, bleeding gums, loose teeth, fragile bones, lesions in bone marrow, sterility, respiratory and intestinal infections, paralysis, hypertrophy of adrenals, gastric ulcers, colitis, erythema, soreness of mouth, indigestion, constipation, headache, anorexia, dermatitis, redness of tongue, glossitis, diarrhea, insanity, poor memory, muscular rearrangements and disorders, retarded growth, edema, muscle incoordination, "fatty" livers, microcytic hypochromic anemia, lesions of various tissues, ophthalmia, abscesses, epileptiform fits, low fertility, impaired placental function, muscle dystrophy, degenerative diseases of the nervous system, graying of the hair, hemorrhagic adrenals, low blood calcium, low blood phosphate, "bow legs," poor deposition of lime and phosphorus in teeth and bones, restlessness, lack of vigor, poor growth, enlarged joints, curved spine, beaded ribs, retarded growth, lesions in bones and teeth, and tetany. These conditions commonly and usually result from causes other than lack of the vitamin substances contained in the article, and the article would not ordinarily correct and relieve such conditions.

DISPOSITION: October 1, 1946. Pleas of guilty having been entered, the defendants were each fined \$200, plus costs.

2160. Adulteration of digitalis tablets. U. S. v. Strong, Cobb and Company, Inc.
Plea of guilty. Fine, \$500 and costs. (F. D. C. No. 21498. Sample No. 10590-H.)

INFORMATION FILED: December 19, 1946, Northern District of Ohio, against Strong, Cobb and Company, Inc., a corporation, Cleveland, Ohio, charging the defendant with the giving of a false guaranty. The guaranty was given by the defendant to the Buffalo Pharmacal Company, Buffalo, N. Y., on or about August 11, 1941. It provided that the article comprising each shipment or delivery made by Strong, Cobb and Company, Inc., would be neither adulterated nor misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On or about August 7, 1945, the defendant sold and delivered a quantity of *digitalis tablets* to the Buffalo Pharmacal Company, and on or about September 25, 1945, the Buffalo Pharmacal Company shipped a bottle containing a quantity of these *digitalis tablets* from the State of New York into the State of Pennsylvania. The tablets so guaranteed and shipped were adulterated and misbranded.

LABEL, IN PART: "Tablets Digitalis U. S. P. XII 1½ grs."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Digitalis Tablets," a drug the name of which is recog-

nized in the United States Pharmacopoeia, an official compendium, and the amount of powdered digitalis contained in the article varied more than 25 percent from the labeled amount of powdered digitalis. The tablets contained less than 75 percent of the labeled amount of powdered digitalis, whereas the compendium provides that "Digitalis tablets shall be considered to conform to the Pharmacopoeia requirement if the result of the assay does not vary more than 25 percent from the labeled amount of powdered digitalis." The difference in the strength of the article from the standard set forth in the official compendium was not plainly stated, or stated at all, on the label.

DISPOSITION: March 31, 1947. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$500, plus costs.

2161. Adulteration of Diet Tablets. U. S. v. 63 Bottles * * *. (F. D. C. No. 21974. Sample Nos. 65559-H, 65571-H, 65572-H.)

LIBEL FILED: December 12, 1946, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: April 29 and May 6, 1946, by National Drug Laboratories, Inc., from Chicago, Ill.

PRODUCT: 63 1,000-tablet bottles of *Diet Tablets* at Philadelphia, Pa.

LABEL, IN PART: "Diet Tablets (Pink) * * * Atropine Sulphate 1/360 Grain."

NATURE OF CHARGE: Adulteration. Section 501 (c), the strength of the article differed from that which it was represented to possess since some tablets of the article contained 13/360 grain of atropine sulfate, although the label declared 1/360 grain of atropine sulfate to be present in each tablet.

DISPOSITION: March 4, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2162. Adulteration of histamine acid phosphate. U. S. v. 84 Vials * * *. (F. D. C. No. 22156. Sample No. 66109-H.)

LIBEL FILED: January 6, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 30, 1946, by Medicinals, Inc., from Richmond Hill, N. Y.

PRODUCT: 84 10-cc. vials of *histamine acid phosphate* at Philadelphia, Pa. Examination showed that the product was contaminated with undissolved material. The United States Pharmacopoeia requires that injections be free of any turbidity or undissolved material which can be detected readily under certain specified conditions.

LABEL, IN PART: "Sterile Solution Histamine Acid Phosphate."

NATURE OF CHARGE: Adulteration. Section 501 (b), the article purported to be and was represented as "Histamine Acid Phosphate Injection," the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth in that compendium.

DISPOSITION: March 4, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2163. Adulteration and misbranding of Lactobacillus acidophilus. U. S. v. 34 Bottles * * *. (F. D. C. No. 22446. Sample No. 59467-H.)

LIBEL FILED: January 30, 1947, Western District of Washington.

ALLEGED SHIPMENT: Shipment on or about December 3, 1946, by Kovac Laboratories, from Los Angeles, Calif.

PRODUCT: 34 8-fluid-ounce bottles of *Lactobacillus acidophilus* at Seattle, Wash.

LABEL, IN PART: "Kovac Type Lactobacillus Acidophilus A condensed culture in whey broth."

NATURE OF CHARGE: Adulteration, section 501 (b), a substance, streptococci, had been mixed with the article so as to reduce its quality and strength and had been substituted in part for the article.

Misbranding, Section 502 (a), the label statement "culture Lactobacillus Acidophilus A condensed culture" was false and misleading as applied to this product which contained relatively few bacillus acidophilus organisms and large numbers of streptococci.

DISPOSITION: On April 11, 1947, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2164. Adulteration of ampules of sodium salicylate and iodide with colchicine.
U. S. v. 32 Boxes * * *. (F. D. C. No. 19571. Sample No. 35944-H.)

LIBEL FILED: On or about April 10, 1946, Western District of Missouri.

ALLEGED SHIPMENT: On or about December 3, 1945, by the National Drug Company, from Philadelphia, Pa.

PRODUCT: 32 25-ampule boxes of *ampules of sodium salicylate and iodide with colchicine* at St. Joseph, Mo.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampules of Sodium Salicylate and Iodide with Colchicine," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: August 20, 1946. Default decree of destruction.

2165. Adulteration of ampules of sodium thiosulfate. U. S. v. 168 Ampules * * *. (F. D. C. No. 12690. Sample No. 81332-F.)

LIBEL FILED: On or about July 1, 1944, District of Kansas.

ALLEGED SHIPMENT: On or about May 8, 1944, by Henry C. Haist and Co., from Kansas City, Mo.

PRODUCT: 158 10-milliliter-size *ampules of sodium thiosulfate*, at Wichita, Kans.

LABEL, IN PART: "A Sterile Isotonic Solution Compounded Especially for Intravenous Administration."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampules of Sodium Thiosulfate," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: June 25, 1944. The consignee, the sole intervenor, having filed an answer admitting that the product was adulterated as alleged in the libel, judgment of condemnation was entered and the product was ordered destroyed.

2166. Adulteration of theelin in oil. U. S. v. 116 Packages * * *. (F. D. C. No. 21110. Sample No. 49472-H.)

LIBEL FILED: September 26, 1946, Northern District of Alabama.

ALLEGED SHIPMENT: On or about June 7, 10, and 20, 1946, by Parke, Davis & Co., from Detroit, Mich.

PRODUCT: 116 packages, each containing 50 ampules, of *theelin in oil* at Birmingham, Ala. Analysis showed that the product contained not less than .7 milligram of theelin (ketohydroxy estratriene) and possessed a potency of not less than 7,000 International Units per cubic centimeter.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, i. e., .5 milligram theelin ketohydroxy estratriene per cubic centimeter (5,000 International Units).

DISPOSITION: April 16, 1947. Parke, Davis & Company, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for reprocessing and disposal under the supervision of the Federal Security Agency.

2167. Adulteration and misbranding of Jarmilla Scalp Conditioner. U. S. v. 289 Jars * * *. (F. D. C. No. 22185. Sample No. 64763-H.)

LIBEL FILED: January 15, 1947, District of New Jersey.

ALLEGED SHIPMENT: On or about August 28 and October 19, 1946, by Jarmilla Products, Inc., from Lake Worth, Fla.

PRODUCT: 225 5½-ounce jars and 64 2-ounce jars of *Jarmilla Scalp Conditioner* at Elizabeth, N. J. Examination showed that the product consisted essentially of yellow mercuric oxide in an ointment base. The smaller size jars of the product contained less than the declared 5 percent of mercuric

oxide, and bacteriological examination showed that the article was not a germicide.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, i. e., by the designation "Germicidal Preparation."

Misbranding, Section 502 (a), the label statement "Scalp Conditioner A Germicidal Preparation for the Treatment of Scalp Disorders" was false and misleading since the article was not a germicide, was not effective for conditioning the scalp, and would not be effective in the treatment of scalp disorders; and, Section 502 (e) (2), the 2-ounce size jar failed to bear a statement of the quantity or proportion of the derivative of mercury contained in the article since the label statement "Mercuric Oxide Yellow U. S. P. 5%" was incorrect.

DISPOSITION: May 5, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2168. Adulteration and misbranding of prophylactics. U. S. v. 23½ Gross * * *. (F. D. C. No. 22632. Sample No. 61322-H.)

LIBLE FILED: March 13, 1947, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 14, 1947, by the World Merchandise Exchange and Trading Co., from New York, N. Y.

PRODUCT: 23½ gross of rubber *prophylactics* at Pittsburgh, Pa. Examination of 200 samples showed that 4.5 percent were defective in that they contained holes.

LABEL, IN PART: "Lloyd's Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the statement "Prophylactics" was false and misleading as applied to an article which contained holes.

DISPOSITION: April 23, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

2169. Misbranding of estrogenic substances. U. S. v. Harvey Laboratories, Inc., and Aaron Lichten. Pleas of nolo contendere. Fines of \$150 against the corporation and \$1 against the individual. (F. D. C. No. 21424. Sample Nos. 5150-H, 7816-H, 8301-H.)

INFORMATION FILED: January 16, 1947, Eastern District of Pennsylvania, against Harvey Laboratories, Inc., Philadelphia, Pa., and Aaron Lichten, treasurer of the corporation.

ALLEGED SHIPMENT: On or about October 19 and 30 and November 1, 1945, from the State of Pennsylvania into the States of New Jersey and New York.

LABEL, IN PART: (Cartons—all shipments, and vials—1 shipment) "Estrogenic Substances [or "Substance"] * * * estrogenic hormones from natural sources, consisting chiefly of estrone with traces of estradiol and auxiliary follicular hormones"; (ampules—2 shipments) "Estrogenic Substance 10,000 [or "50,000"] International Units Per cc."

NATURE OF CHARGE: Misbranding, Section 502 (a), the above-quoted statements on the cartons and vial labels were false and misleading since they represented and suggested that the article consisted chiefly of estrone, whereas it did not consist chiefly of estrone.

Further misbranding, Section 502 (e), the article was not designated solely by a name recognized in an official compendium; it was fabricated from 2 or more ingredients; and the ampule labels failed to bear the common or usual name of each active ingredient, since the designation "Estrogenic Substance" is not the common or usual name of any particular active ingredient but is a generic name for a class of substances.

* See also Nos. 2151, 2153-2155, 2158, 2159, 2163, 2167, 2168.

DISPOSITION: March 14, 1947. Pleas of nolo contendere having been entered, the court imposed fines of \$150 against the corporation and \$1 against the individual.

2170. Misbranding of Devonshire's Earth Salts. *U. S. v. Harry C. Johnson (F. S. Powers & Company). Plea of guilty. Fine, \$20.* (F. D. C. No. 14238. Sample Nos. 8429-F, 8430-F.)

INFORMATION FILED: June 13, 1945, Northern District of Illinois, against Harry C. Johnson, trading as F. S. Powers & Company, Crystal Lake, Ill.

ALLEGED SHIPMENT: On or about February 17 and March 18, 1944, from the State of Illinois into the State of Wisconsin.

PRODUCT: Analyses disclosed that the product was a fine white powder consisting essentially of carbonates, phosphates, chlorides, sulfates of calcium, sodium, magnesium, and iron, and small amounts of free sulfur, silica, and fluorine compounds.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying circulars entitled "Devonshire's Earth Salts Mineral Elements" and "Devonshire's Earth Salts Mineral Elements a Compound of the Life Giving Mineral Elements of Mother Nature" were false and misleading in that they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of appendicitis, trench mouth, skin disorders, sinus disorders, stomach troubles, a run-down condition, Bright's disease, diabetes, high blood pressure, poor eyesight, kidney trouble, backache, dizzy spells, swelling in legs, brown spots on the face, colitis, sinus headache, neuritis, rheumatism, an anemic condition, gall-bladder trouble, palpitation of the heart, leakage of the heart, breaking out of the face, bad condition of stomach and bowels, eczema, boils, and periodic pains; that it would be effective as a body builder; that it would supply pep, increase weight, strengthen the body, increase vitality and energy, cure anyone who was ill, clean and strengthen the system, prevent colds, renew health, give life, prevent and remedy abnormal disease conditions which cause untold suffering and misery to the human race, help the body wage its war against disease, and cure the sick; and that it would be beneficial for relief in treating rheumatism, lumbago, sciatica, neuritis, intestinal disorders, kidneys, spleen, liver, bladder, diabetes, goiter, gall trouble, skin disorders, eczema, stomach ulcers, nervous disease, and bronchitis. The article would not be efficacious for the purposes represented.

DISPOSITION: January 27, 1947. At the request of the defendant, the case was transferred for plea to the Southern District of California. Thereafter, a plea of guilty was entered and the court imposed a fine of \$10 on each of the 2 counts of the information.

2171. Misbranding of Devonshire's Earth Salts. *U. S. v. Harry C. Johnson (F. S. Powers & Company). Plea of not guilty. Tried to the jury. Verdict of guilty. Fine, \$10.* (F. D. C. No. 17861. Sample No. 17400-H.)

INFORMATION FILED: May 10, 1946, Southern District of California, against Harry C. Johnson, trading as F. S. Powers & Company, Los Angeles, Calif.

ALLEGED SHIPMENT: On or about May 25, 1945, from the State of California into the State of Wisconsin.

PRODUCT: Examination disclosed that the product consisted essentially of carbonates, sulfates, chlorides, and phosphates of calcium, sodium, iron, and magnesium, and a small proportion of sulfur.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in circulars entitled "Devonshire's Earth Salts Mineral Elements" and in a manual bearing on its cover the words "Devonshire's Earth Salts," which accompanied the article, were false and misleading since the statements represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of rheumatism, anemia, cold, sinus disorders, appendicitis, diabetes, skin diseases, underweight, constipation, a general run-down condition, eczema, mineral deficiency diseases, colitis, stomach trouble, sinus headache, gall-bladder trouble, palpitation of the heart, leakage of the heart, Bright's disease, high blood pressure, poor eyesight, backache, dizzy spells, swelling of legs, painful boils, periodic pains, kidney and bladder trouble, ulcers of the stomach, piles, boils, ulcer of the intestines, pyorrhea, nervous break-down, menstrual cramps,

nervousness, restlessness, sleeplessness, lack of pep, lack of ambition, headaches caused by constipation, lumbago of neck and shoulders, drowsiness after eating, failing health, excessive acid stomach, intestinal flu, overweight conditions, trench mouth, skin disease including those that are seldom curable, weakness, rheumatoid arthritis, neuritis, chronic diarrhea, beginning of insanity, hardening of the arteries, ununited fractures, pain in the bladder, cancer of the bladder, low blood pressure, erysipelas, swollen hands and knees, dropsy of the blood, liver trouble, pains in the legs, epileptic fits, prostate gland trouble, and acute appendicitis; that it would cleanse and strengthen the entire system and cause all organs of the body to function properly; that it was a great body cleaner and builder; and that it would be efficacious as a body builder and beauty treatment and in reconditioning the system. The article would not be efficacious for such purposes.

DISPOSITION: January 27, 1947. The defendant having entered a plea of not guilty, the case came on for trial before a jury on July 23, 1946. On July 26, 1946, the trial was concluded, and the jury returned a verdict of guilty. On January 27, 1947, the court imposed a fine of \$10.

2172. Misbranding of Loca Septo. U. S. v. Clem A. Conaway (Loca Septo Co.). Plea of guilty. Fine, \$50 and costs. (F. D. C. No. 20183. Sample Nos. 16773-H, 19401-H.)

INFORMATION FILED: November 13, 1946, Southern District of Iowa, against Clem A. Conaway, trading as the Loca Septo Co., Des Moines, Iowa.

ALLEGED SHIPMENT: The drug was shipped on or about December 18, 1944, and July 20, 1945, from the State of Iowa into the States of Illinois and Minnesota. In addition, the defendant shipped between the approximate dates of May 1 and July 21, 1945, a number of display cards entitled "For Healthy Feet Loca Septo" and a number of pamphlets entitled "Loca Septo."

PRODUCT: Analysis showed that the product consisted essentially of an aromatic, yellow-brown, oily liquid containing petroleum oil and small amounts of aromatic hydrocarbons such as xylol and toluene, and cresols.

LABEL, IN PART: "Loca Septo A Mineral Oil Containing Hydrocarbons of Coal, Anthracene, Cresols, Xylol, Naphtholene and Toluol."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and display cards and in pamphlets were false and misleading. These statements represented and suggested that the article would be efficacious in the treatment of infected parts, trench foot, athlete's foot, bunions, corns, bruises, sprains, parasitical and fungi infections, all types of infection, dry sockets, trench mouth or unfavorable reaction in dental surgery, neuritis, hemorrhoids, arthritis, gangrene infection, bed sores, all kinds of itching and skin diseases, ringworm, psoriasis, and barber's itch; that it was an antiseptic and germicide; that it possessed healing power; and that it would be conducive to foot health. The article would not be efficacious for the purposes and conditions stated and implied; it was not an antiseptic and germicide; it did not possess healing power; and it would not be conducive to foot health.

DISPOSITION: On April 28, 1947, a plea of guilty having been entered by the defendant, the court imposed a fine of \$50, plus costs.

2173. Misbranding of Sharp's Salve. U. S. v. William B. Sharp (Sharp's Salve Manufacturing Co.). Plea of guilty. Fine, \$100 and costs. (F. D. C. No. 21436. Sample Nos. 19170-H, 66820-H.)

INFORMATION FILED: February 6, 1947, Southern District of Iowa, against William B. Sharp, trading as the Sharp's Salve Manufacturing Co., Des Moines, Iowa.

ALLEGED SHIPMENT: A number of jars of the product, together with a quantity of letters and a number of leaflets entitled "Sharp's Salve Made and Recommended for Man or Beast," were shipped on or about March 18, 1945, from the State of Iowa into the State of Illinois; and one jar of the product, around which was wrapped the aforementioned letter, was shipped on or about February 10, 1946, from the State of Iowa into the State of Nebraska.

PRODUCT: Examination showed that the product was a soft, yellow ointment containing essentially a fatty, saponifiable base, resinous and waxy material, reducing sugars, turpentine, linseed oil, and protein.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the letter which accompanied both shipments of the article and in the leaflet accompanying the first-mentioned shipment were false and misleading since they represented, suggested, and created in the mind of the reader the impression that the article would be efficacious in the treatment of piles, eczema, boils, burns, diseases and disorders of the prostate gland, carbuncles, old sores, cuts, blood poison, infection, fistula, tired and frosted feet, bruises, erysipelas, sprains, scurvy, and itch; that it would restore and maintain good health; that it would be efficacious in the treatment of common ailments and puncture wounds of the foot; that it would correct frequency of urination; and that its use would keep one out of hospitals, would keep one from having expensive operations, and would give one better health. The article would not be efficacious for the purposes represented and suggested.

DISPOSITION: April 28, 1947. A plea of guilty having been entered by the defendant, the court imposed a fine of \$100, plus costs.

2174. Misbranding of Tarbonis. U. S. v. 48 Jars and 45 Jars * * * and a number of circulars and booklets. (F. D. C. No. 20805. Sample No. 1660-H.)

LIBEL FILED: September 16, 1946, Middle District of North Carolina.

ALLEGED SHIPMENT: From Cleveland, Ohio, by the Tarbonis Company. The product and a number of the circulars and booklets were shipped on or about September 19, 1945, and the remainder of the circulars were shipped on or about March 1, 1946.

PRODUCT: 48 2 1/4-ounce jars and 45 1-pound jars of *Tarbonis* at Lexington, N. C., together with 200 circulars entitled "Right Out of This World," 500 circulars entitled "The Pioneer That Made Tar Acceptable," 12 circulars entitled "In Stubborn Skin Conditions," and 7 booklets entitled "Tarbonis." Analysis showed that the product consisted essentially of coal tar, menthol and oil of lemon in a greaseless ointment base.

LABEL, IN PART: "Tarbonis Liquor Carbonis Detergens (Special Process) 5% Lanolin and Menthol Incorporated in a Greaseless Cream."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and the designs of various skin diseases, appearing on the label of the article and in the circulars and booklets, were false and misleading since they represented and suggested that the article would be effective in the prevention and treatment of occupational dermatitis, eczema, infantile eczema, seborrheic dermatitis, tinea corporis, intertrigo, indolent ulcers, industrial dermatoses, ulcus, cruris, psoriasis, infectious eczematoid dermatitis, ringworm, folliculitis, pityriasis, varicose ulcers, tinea cruris, lichen simplex chronicus, trichophytosis corporis, leg ulcers, and a host of other cutaneous disorders; that it would be effective against a wide array of occupational irritants; that it would act as a preventive when systematically used as a prophylactic; that it would correct stagnation of the blood serum in the tissues and trophic ulcer formation; that it would cause decongestion and improvement of the lymph space circulation; that it would interrupt the vicious circle of stagnation and increase local edema; and that it would restore adequate nutrition to the affected area and initiate healing. The article would not be effective for the purposes so represented and suggested.

DISPOSITION: July 8, 1947. The Tarbonis Company, claimant, having failed to file an answer in the matter, judgment of condemnation was entered and the product was ordered destroyed.

2175. Misbranding of Nanette Hormone Cream. U. S. v. 49 Jars * * *. (F. D. C. No. 22597. Sample No. 50260-H.)

LIBEL FILED: March 4, 1947, Northern District of Alabama.

ALLEGED SHIPMENT: On or about April 30 and October 2, 1946, by the Nix Cosmetics Company, from Memphis, Tenn.

PRODUCT: 39 2-ounce jars and 10 6-ounce jars of *Nanette Hormone Cream* at Birmingham, Ala. Examination showed that the product was an ointment containing 4.9 milligrams of diethylstilbestrol per 2 ounces.

LABEL, IN PART: "Nanette Hormone Cream."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Hormone Cream" and the labeled statement "Each 2 ozs. contains 5 mgs. stilbestrol (synthetic

estrogenic substance)" were false and misleading since they represented, suggested, and created the impression that the article contained a hormone and that it would exert a beneficial hormone-like or beneficial estrogenic effect upon the body when used according to the directions "Apply gently $\frac{1}{2}$ heaping teaspoonful at bedtime. Leave on overnight." The article did not contain a hormone and would not produce a beneficial hormone-like or beneficial estrogenic effect when used as directed.

DISPOSITION: April 14, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2176. Misbranding of Theradophilus Culture. U. S. v. 14 Cases and 6 Bottles
* * *. (F. D. C. No. 20555. Sample No. 59441-H.)

LIBEL FILED: July 24, 1946, Western District of Washington.

ALLEGED SHIPMENT: On or about February 14 and 19 and April 23 and 27, 1946, by Therapy, Limited, from Pasadena, Calif.

PRODUCT: 14 cases, each containing 24 bottles, and 6 bottles of *Theradophilus Culture* and a number of booklets entitled "Therapy Supplementary Foods" at Seattle, Wash. Examination showed that the article contained not more than 1 million viable acidophilus organisms per cubic centimeter.

LABEL, IN PART: "Theradophilus A Culture of Bacillus Acidophilus in Soya Bean Medium Contents 8 Fl. Oz. * * * Directions: Take one tablespoonful in half a glass of water at least half an hour before breakfast and again at bedtime. For infants: One teaspoonful in milk, once a day."

NATURE OF CHARGE: Misbranding, Section 502 (a), the directions on the bottle label were false and misleading since they represented and suggested that the article when taken as directed would supply a significant amount of acidophilus organisms, whereas it would not supply a significant amount of such organisms when taken as directed; and, further, certain statements in the booklet accompanying the article were false and misleading. These statements represented and suggested that the article would be effective for controlling conditions in the intestines, be conducive to longevity, and be effective to accomplish great improvement in health, whereas it would not be effective for such purposes.

DISPOSITION: September 18, 1946. Default decree of condemnation and destruction.

2177. Misbranding of Acidofilac. U. S. v. 81 Bottles * * * and a number of circulars. (F. D. C. No. 21679. Sample No. 59465-H.)

LIBEL FILED: November 26, 1946, Western District of Washington.

ALLEGED SHIPMENT: On or about October 1, 1946, by the Radiance Products Company, from Los Angeles, Calif.

PRODUCT: 81 pint bottles of *Acidofilac* and a number of circulars entitled "Fight The Invisible Foe in Your Intestine" at Seattle, Wash. Examination showed that the product contained two strains of viable lactobacilli.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements appearing in the labeling of the article were false and misleading since they represented and suggested that the use of *Acidofilac* would be effective to control and overcome unfriendly bacteria, kill the putrefactive bacteria in the intestines and prolong life, and affect the general health. The use of *Acidofilac* would not be effective for such purposes.

DISPOSITION: February 11, 1947. No claimant having appeared, judgment of condemnation was entered and the product and circulars were ordered destroyed.

2178. Misbranding of Prostall. U. S. v. 22 Bottles * * *. (F. D. C. No. 22616. Sample No. 63119-H.)

LIBEL FILED: March 11, 1947, Northern District of California.

ALLEGED SHIPMENT: On or about February 3, 1947, by Douglas Laboratories, from Boston, Mass.

PRODUCT: 22 100-capsule bottles of *Prostall* at San Francisco, Calif.. Analysis showed that the product consisted essentially of glutamic acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Prostall 'stalls off pain,' relieves the symptoms of prostate hypertrophy (pro-

titis). Relief starts in a few days and improvement continues thereafter. Prostall permanently relieves some cases. However, it is primarily a pain-reducer in time" were false and misleading since the article would not be effective in the relief of pain in prostate hypertrophy.

Further misbranding, Section 502 (e) (1), the label of the article failed to bear the common or usual name of the drug.

DISPOSITION: April 29, 1947. Default decree of condemnation and destruction.

2179. Misbranding of Apiphene. U. S. v. 48 Dozen Jars * * *. (F. D. C. No. 22236. Sample No. 64717-H.)

LIBLE FILED: February 5, 1947, Southern District of New York.

ALLEGED SHIPMENT: Between the approximate dates of September 25 and December 2, 1946, by the Hatfield Laboratories, from Tucson, Ariz.

PRODUCT: 48 dozen jars of *Apiphene* at New York, N. Y. Examination showed that the product consisted essentially of beeswax mixed with some honey.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in circulars entitled "Information on Apiphene Homogenized Comb Honey" and "Information on Apiphene Summary of Research," shipped with the article, were false and misleading since they represented and suggested that the article would be effective in the treatment and prevention of hay fever, sinusitis, asthma, catarrhal deafness, chronic and common colds, and other disorders of the respiratory tract; that it would be effective in promoting an easy rising of the sputum in cases of tuberculosis; and that it would be effective to benefit the respiratory tract, glands of the head and throat, general mucosa, and the glands which control the mucosa of the entire respiratory tract. The article would not be effective for such purposes.

DISPOSITION: June 2, 1947. Hettie Hamper, New York, N. Y., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

2180. Misbranding of Boncquet Tablets. U. S. v. 31 Bottles * * * and a number of circulars. (F. D. C. No. 19735. Sample No. 23395-H.)

LIBLE FILED: May 1, 1946, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about February 16, 1946, by Boncquet Laboratories, from Glendale, Calif.

PRODUCT: 22 75-tablet bottles and 9 200-tablet bottles of *Boncquet Tablets* and a number of circulars entitled "Good News for Tired, Head-Achy Run-Down Men and Women."

LABEL, IN PART: "Boncquet (Bon-Kay) Tablets * * * Vitamin B Complex with Iron and Vitamin A, C, and D."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and designs in the circular which accompanied the article were false and misleading since they represented and suggested that the article would be effective to provide substances in the formation of blood which are not readily available from common foods; that it would be effective to insure vitality and buoyant health; that it would be effective in the treatment and prevention of tiredness, nervousness, headaches, pains, colds, infections, tooth decay, poor vision, debility, eye troubles, muscular weakness, abnormal changes in the structure of body cells, poor appetite, constipation, flatulence, dyspepsia, lack of stamina, loss of weight, poor hearing, skin disorders, pyorrhea, poor wound healing, digestive disturbances, pneumonia, and baldness; that widespread dietary deficiencies exist in the ingredients supplied by the article; that the ordinary individual can obtain adequate quantities of vitamins and minerals only by exercising extreme care in the selection of diets; and that foods in general are unsatisfactory sources of essential nutrients, and therefore the use of the product would be almost essential. The article would not be effective for those purposes; widespread dietary deficiencies do not exist in the ingredients supplied by the article; the regular diet of ordinary individuals supplies adequate quantities of vitamins and minerals; and foods in general are satisfactory sources of essential nutrients, and the use of the article would therefore not be essential.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: June 6, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2181. Misbranding of Parsley and Garlic capsules, etc. U. S. v. 15½ Dozen Bottles * * *, etc., and a number of circulars. (F. D. C. No. 21945. Sample Nos. 36178-H to 36183-H, incl., 36185-H to 36192-H, incl.)

LIBLE FILED: On or about December 30, 1946, Western District of Missouri.

ALLEGED SHIPMENT: Between the approximate dates of February 6 and October 31, 1946, by the Battle Creek Dietetic Supply Company, from Battle Creek, Mich.

PRODUCT: 15½ dozen 120-capsule bottles of *Parsley and Garlic*, 18½ dozen 60-capsule bottles of *Hi-A Vitamin*, 17 dozen 50-capsule bottles of *Soy Bean Lecithin with Vitamin D*, 35½ dozen 100-tablet bottles of *Vitamin C 100 Mgm.*, 23 dozen 100-tablet bottles of *Riboflavin Vitamin B₂ (G)*, 23½ dozen 150-tablet bottles of *Vitamin B Complex Ironated*, 19½ dozen 1-pint bottles of *Malt Syrup with Vitamins A B D*, 29½ dozen 1-pint bottles of *Vitamin and Mineral Compound*, 36 dozen 1-pound bottles of *Lactose Dextrans Maltose with Dry Lemon Juice*, 32 dozen 500-tablet packages of *Kelp Tablets*, 35 dozen 1-pound cans of *Wheat Germ*, 24¼ dozen 60-wafer packages of *Dicalcium Phosphate Wafers with Viosterol*, 36½ dozen 70-capsule and 140-capsule bottles of *Tonique Capsules*, 21¼ dozen 60-capsule bottles and 17¾ dozen 150-capsule bottles of *Wheat Germ Oil*, and a number of circulars entitled "Health is Wealth" at North Kansas City, Mo.

Examination showed that the *Parsley and Garlic* capsules consisted essentially of garlic, parsley, an oil, and iron; that the *Hi-A Vitamin* capsules consisted essentially of vitamin A in oil; that the *Soy Bean Lecithin with Vitamin D* consisted essentially of lecithin and vitamin D in oil; that the *Vitamin C 100 mgm.* was a white tablet containing vitamin C; that the *Riboflavin Vitamin B₂ (G)* was a black tablet containing riboflavin; that the *Vitamin B Complex Ironated* tablets contained riboflavin, vitamin B₁, a calcium salt, and iron; that the *Malt Syrup with Vitamins A B D* was a viscous liquid containing vitamins A, B₁, and D, and iron; that the *Vitamin and Mineral Compound* was a brown liquid containing vitamins A, B₁, and D, calcium, phosphorous, and iron; that the *Lactose Dextrans Maltose with Dry Lemon Juice* consisted essentially of a lemon-flavored mixture of lactose, dextrans, and maltose; that the *Kelp Tablets* were gray compressed tablets containing small amounts of calcium, iron, and iodine; that the *Wheat Germ* was a yellow powder having the appearance of wheat germ; that the *Dicalcium Phosphate Wafers with Viosterol* was a light brown wafer containing vitamin D, calcium, and phosphorous; that the *Tonique Capsules* consisted essentially of vitamin B₁ and iron; and that the *Wheat Germ Oil* was a yellow saponifiable oil having the appearance of wheat germ oil.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label designation "Health House" was false and misleading since it created the impression that the articles were effective to insure health, whereas they would not be effective for that purpose.

Further misbranding, Section 502 (a), certain statements in the circular accompanying the articles were misleading since they represented and suggested that the articles, when used separately or in combination, were effective to protect the health and compensate for inadequate food intake, to prevent and correct constipation, and to make the user mentally and physically vigorous. The articles, when used separately or in combination, would not be effective for such purposes.

Further misbranding, Section 502 (a), certain statements which appeared in the circular accompanying the articles were false and misleading since these statements represented and suggested that the articles would be effective in the treatment of the following diseases, symptoms, and conditions stated and implied: (*Parsley and Garlic*) " * * * * for the relief of the distressing symptoms—headache, dizziness, involuntary naps, tiredness, sluggishness * * * *"; (*Hi-A Vitamin*) " * * * * Indicated in night blindness and respiratory infections * * * *"; (*Soy Bean Lecithin with Vitamin D*)

"NERVES ARE EXPENSIVE Health is too precious to risk it with 'jitters.' Food is too valuable to waste because of nervous indigestion. If something keeps up a turmoil preventing self-mastery, tell your doctor. Get your rest. After your daily job, relax. **BALANCE THE DIET.** Relieve constipation. Insure optimum intake of minerals and vitamins, especially vitamin B. * * * Phosphorus and lecithin are important to the nerves. Nerve tension can be relieved by the use of Soy Bean Lecithin to the extent that a possible phosphorus deficiency is relieved * * *"; (*Vitamin C 100 Mgm.*) " * * * a deficiency of vitamin C may contribute to hay fever, poor teeth and bones, and skin troubles * * *"; (*Riboflavin Vitamin B₂ (G)*) " * * * Sometimes referred to as the growth vitamin. A deficiency may cause skin disorders, digestive disturbances and nervous symptoms * * *"; (*Vitamin B Complex Ironated*) " * * * Chronic partial Vitamin B deficiency is probably one of the factors in the production of the constipation so commonly met with among Western people, and other signs and symptoms of Chronic gastro-intestinal malfunction in adults * * *"; (*Vitamin and Mineral Compound*) " * * * for children with retarded growth due to lack of appetite and lack of Vitamin A and B * * *"; (*Lactose Dextrins Maltose with Dry Lemon Juice*) " * * * With intestinal cleanliness regained, the bowels should be more regular, the breath sweeter, the complexion clearer, eyes brighter and an increased sense of physical fitness experienced * * *"; (*Wheat Germ*) " * * * a rich source of Vitamin B * * * Also contains vitamin A, E, and G. Vitamin B is but sparingly stored in the body so it must be supplied by the food each day * * * functions * * * 1. Promoting the utilization of food by the body tissues (called metabolism). 2. Aiding the process of lactation in nursing mothers. 3. Toning up the digestive muscles and thus promoting normal elimination. 4. For fitness and general well-being * * *." The articles would not be effective in the treatment of the diseases, symptoms, and conditions stated and implied.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 27, 1947. The Battle Creek Dietetic Supply Company having appeared as claimant, judgment of condemnation was entered and the products were ordered released under bond, with the exception of the pamphlets entitled "Health is Wealth," conditioned that they be brought into compliance with the law, under the supervision of the Food and Drug Administration. The pamphlets were ordered destroyed.

2182. Misbranding of Macia Nose Drops. U. S. v. 52 Bottles * * *. (F. D. C. No. 21685. Sample No. 57603-H.)

LIBEL FILED: December 12, 1946, District of Rhode Island.

ALLEGED SHIPMENT: On or about February 13, 1946, by Macia Corporation, from Holyoke, Mass.

PRODUCT: 52 1-oz. bottles of *Macia Nose Drops* at Providence, R. I. Examination showed that the product consisted essentially of water, chlorobutanol, and salt, colored with an orange dye.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements, appearing in the labeling of the article, i. e., on the carton and bottle labels, in the leaflet entitled "Yes, You Can Beat a Cold," and on the circular entitled "Sinus Sufferers Attention," which leaflet and circular were enclosed with the retail carton, were false and misleading since they represented and suggested that the article would be effective in the relief of sinus, hay fever, colds, rhinitis, nasal congestion, and sore throat, and in restoring the natural flow and function of the nasal secretions. The article would not be effective for such purposes.

DISPOSITION: April 7, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2183. Misbranding of Reduco Bath Crystals. U. S. v. 14 Packages * * *. (F. D. C. No. 22279. Sample No. 54696-H.)

LIBEL FILED: February 12, 1947, Southern District of Florida.

ALLEGED SHIPMENT: On or about August 29, 1946, by Ann J. MacHale, Inc., from New York, N. Y.

PRODUCT: 14 6-pound packages of *Reduco Bath Crystals* at Jacksonville, Fla. Analysis disclosed that the product consisted essentially of sodium sesquicarbonate, colored blue and perfumed.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Reduco Bath * * * A Reducing Aid without Exercise * * * Aid for Rheumatism and Arthritis" were false and misleading since the article would not be effective in removing superfluous weight or in the treatment of rheumatism or arthritis.

DISPOSITION: June 17, 1947. Default decree of condemnation and destruction.

2184. Misbranding of Yardley Hair Tonic. U. S. v. 42 Bottles * * *. (F. D. C. No. 16383. Sample No. 6662-H.)

LIBEL FILED: June 18, 1945, Southern District of New York.

ALLEGED SHIPMENT: On or about February 14, 1945, by Yardley of London, Inc., from Union City, N. J.

PRODUCT: 42 11-ounce bottles of Yardley Hair Tonic at New York, N. Y. Analysis disclosed that the product consisted essentially of water, alcohol, a fatty oil, perfume, and coloring matter.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling were false and misleading: (Bottle) "Hair Tonic Regular use aids in maintaining sturdy hair growth"; (carton) "Hair Tonic * * * Regular use helps to maintain sturdy growth"; (circular) "Hair Tonic * * * Daily massage of the scalp with the finger tips helps to keep the hair healthy * * * If this 'daily dozen' is followed by the application * * * of Yardley Hair Tonic, an encouraging response to the treatment results * * * helping to keep the hair in a healthy condition. * * * Regular use aids in maintaining sturdy hair growth, thus retarding baldness." The article possessed no tonic properties and was not effective in promoting the growth and health of hair or in retarding baldness.

Further misbranding, Section 502 (c), the name and address of the manufacturer "Yardley, 620 Fifth Avenue, New York," which is required under authority of the law to appear on the label, was not prominently placed thereon with such conspicuousness (as compared with other matter on the label) as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

DISPOSITION: January 29, 1947. Yardley of London, Inc., claimant, having withdrawn its answer and having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

2185. Misbranding of Pierce's Slant Health Board. U. S. v. Charles Merritte Pierce (Pierce's Slant Health Board). Plea of nolo contendere. Fine, \$100; defendant placed on probation. (F. D. C. No. 21425. Sample No. 20516-H.)

INFORMATION FILED: December 5, 1946, Southern District of California, against Charles Merritte Pierce, trading as Pierce's Slant Health Board, at Burbank, Calif.; amendment filed April 14, 1947.

ALLEGED SHIPMENT: On or about February 19, 1946, from the State of California into the State of Missouri.

PRODUCT: This device consisted of an exercise board 1½ feet wide by 6 feet long, padded and covered with colored awning material. There was a strap across one end to hold the feet, and there were legs at the strap end which raised one end of the board. While exercising, the user reclined on the board, with the head at the lower end.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a circular entitled "Three in One" and in letters entitled "To the Doctors" and "My Dear Friend," accompanying the article, were false and misleading. These statements represented and suggested that the device would be efficacious to combat wear and tear in the body, to build the body, to rest the overworked heart, and to pull up, strengthen, and keep the organs in place; that it would enable the user to keep fit and to renew vigor; that it would be efficacious to revitalize the cells of the body and awaken the blood stream to renewed activity; that it would get the waste out of the body, renew animation, and give the user the spirit to keep going, and live naturally and healthfully; that it would add years to life, improve the health of the user, and generate elec-

tricity and lactic acid, resulting in a source of great power and strength in the human body; that it would furnish energy and normalize the blood pressure, enable the healthy person to stay well and the sick person to get well, be efficacious as a cure for brain anemia, and stimulate and feed the brain and nerve centers. The device would not be efficacious for the purposes represented.

DISPOSITION: August 18, 1947. A plea of nolo contendere having been entered, the court imposed a fine of \$100 and placed the defendant on probation for 1 year, conditioned upon his compliance with all laws and specifically upon his compliance with the law in regard to the branding of this device and other similar products.

DRUGS FOR VETERINARY USE

2186. Adulteration of Dencol-10. U. S. v. 65 Bottles * * * and a number of circulars. (F. D. C. No. 22134. Sample No. 51679-H.)

LABEL FILED: January 3, 1947, District of Minnesota.

ALLEGED SHIPMENT: The drug was shipped on or about December 14, 1945, and the circulars were shipped at a prior date, by Barlow, Wright & Shores, Inc., from Cedar Rapids, Iowa.

PRODUCT: 65 1-pint bottles of *Dencol-10* and a number of circulars entitled "Dencol-10 (Guaiacol 10%)," at Mankato, Minn. Analysis showed that the article was essentially guaiacol, oil of eucalyptus, gum camphor, and creosote in a mineral oil base.

LABEL, IN PART: "Dencol-10 Indications * * * Distributed by the Denver Serum Company, Cedar Rapids, Iowa."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements appearing on the bottle label and in the circular accompanying the article were false and misleading since they represented and suggested that the article would be effective as an aid for treating simple colds of livestock and poultry; that it would be effective in the treatment of diseases affecting the lungs and air passages by reason of the fact that it would be eliminated by the blood through the lungs; that it would be effective in the treatment of flu in swine, pneumonia and bronchitis in all animals, roup in fowls, and influenza and strangles in horses; that it would aid in controlling pneumonia, in curbing excessive fluids (oedema) of the lungs and chest cavity, and in getting the herd back on full feed; that it would be effective in the control of herd outbreaks of pneumonia and in the treatment of shipping fever and strangles, sore throats, coughs, colds, cattle pneumonia, scours, lung diseases of sheep and lambs, and roup in chickens and turkeys. The article would not be effective for such purposes.

DISPOSITION: March 6, 1947. No claimant having appeared, judgment was entered and the products were ordered destroyed.

2187. Misbranding of Corn King Udder Ointment, Dr. Clark's Udder Salve, Shores Kre-O-Col, and Shores Mul-Ene. U. S. v. Barlow, Wright & Shores, Inc. Plea of guilty. Fine, \$500 and costs. (F. D. C. No. 21434. Sample Nos. 16448-H, 51047-H, 51054-H, 51055-H.)

INFORMATION FILED: August 18, 1947, Northern District of Iowa, against Barlow, Wright & Shores, Inc., Cedar Rapids, Iowa.

ALLEGED SHIPMENT: On or about June 8, 1945, and January 14 and February 9, 1946, from the State of Iowa into the States of Illinois, South Dakota, and Minnesota.

PRODUCT: Analyses disclosed that the *Corn King Udder Ointment* was a red opaque salve containing carbolic acid, methyl salicylate, and oil of eucalyptus in an ointment base; that the *Dr. Clark's Udder Salve* was a red opaque salve containing similar ingredients; that the *Shores Kre-O-Col* was a reddish-brown fluid containing guaiacol, oil of eucalyptus, creosote, oil of camphor, isopropyl alcohol, and water; and that the *Shores Mul-Ene* was a green-blue fluid containing zinc phenolsulfonate, manganese sulfate, ammonium phenolsulfonate, ferrous phenolsulfonate, copper phenolsulfonate, copper sulfate, and water.

NATURE OF CHARGE: *Corn King Udder Ointment* and *Dr. Clark's Udder Salve*. Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading in that they represented and suggested that the article

would be an adequate treatment for mastitis. The article would not be an adequate treatment for mastitis.

Shores Kre-O-Col. Misbranding, Section 502 (a), certain statements on the label of the article and in a booklet entitled "Business Building Manual for Poultry Dealers" accompanying the article were false and misleading since they represented and suggested that the article when used as directed would be effective as an aid in relieving mucous accumulations of the nose and throat in poultry; that it would be efficacious in the cure, mitigation, and treatment of colds and bronchitis in poultry and respiratory irritations in poultry due to colds; and that it would aid in relieving bronchial and nasal irritations in poultry arising from colds. The article would not be effective for such purposes.

Shores Mut-Ene. Misbranding, Section 502 (a), certain statements on the label of the article and in the above-named booklet accompanying the article were false and misleading since they represented and suggested that the article would be capable of producing an astringent effect upon the intestinal mucous membranes of poultry, and that it would be effective in the prevention and treatment of coccidiosis in poultry. The article would not be capable of producing such astringent effect, and it would not be effective in the prevention and treatment of coccidiosis in poultry.

DISPOSITION: August 18, 1947. A plea of guilty having been entered, the court imposed a fine of \$125, plus costs, on each of the 4 counts of the information.

2188. Misbranding of General Hog Liquid. U. S. v. General Veterinary Laboratory, Lyman H. Thomas, and C. Coe Buchanan. Pleas of guilty. Fines, \$250 against laboratory and \$50 against each individual. (F. D. C. No. 20108. Sample Nos. 18252-H, 19148-H.)

INFORMATION FILED: July 18, 1946, District of Nebraska, against the General Veterinary Laboratory, a corporation, Omaha, Nebr., Lyman H. Thomas, president, and C. Coe Buchanan, secretary-treasurer of the corporation.

ALLEGED SHIPMENT: On or about March 31, 1945, from the State of Nebraska into the State of Iowa.

PRODUCT: Analysis disclosed that the product consisted essentially of water containing in each 100 cc. 5.0 grams of sodium hydroxide, 4.1 grams of sodium carbonate, 2.4 grams of copper sulfate, 1.4 grams of calcium phosphate, 0.02 gram of potassium iodide, 0.6 cc. of oil of Chenopodium, and arsenic, creosote, and a minute amount of strychnine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and certain statements and designs in a circular entitled "Your Pigs Are in Danger," enclosed with the article, were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of necro, flu, swine plague, mixed infection, wormy conditions, and similar conditions among hogs, indicated by the abbreviation "etc."; that it would prevent pigs from becoming anemic and unthrifty; that it was a 10-ingredient medicine for hog diseases generally; that it would prevent sickness getting a start among hogs; that it would fight sickness, set-backs, and runtiness; that it would prevent losses among hogs and would enable hog raisers to make bigger profits; and that it would "keep the pigs coming along fast every day." The article would not be efficacious for the purposes represented, and it was not a 10-ingredient medicine for hog diseases generally.

DISPOSITION: May 28, 1947. Pleas of guilty having been entered, the court imposed fines of \$250 against the laboratory and \$50 against each individual.

2189. Misbranding of medicated charcoal. U. S. v. Des Moines Incubator Co. and Philip Worth. Pleas of nolo contendere. Fine of \$25 and costs against each defendant. (F. D. C. No. 20171. Sample No. 33158-H.)

INFORMATION FILED: October 23, 1946, Southern District of Iowa, against the Des Moines Incubator Co., a corporation, Des Moines, Iowa, and Philip Worth, president and manager of the corporation.

ALLEGED SHIPMENT: On or about June 19, 1945, from the State of Iowa into the State of Kansas.

PRODUCT: Analysis disclosed that the product consisted of approximately 90 percent charcoal, 7 percent calcium carbonate, 1.5 percent epsom salt, 0.4 percent glauber salt, and a small amount of brown fibrous material.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the circular entitled "Directions for Feeding," which accompanied the article, were false and misleading since they represented and created the impression that the article would be effective in the prevention and treatment of disease conditions in poultry; that the ingredient, charcoal, would be of therapeutic importance in the prevention and treatment of disease; that the article contained glauber salt, white oak bark, and epsom salt in amounts sufficient to be of therapeutic importance in the treatment and prevention of disease when used as directed. The article would not be efficacious for the purposes represented and would not be of therapeutic importance by reason of the stated ingredients, in that the article contained insignificant proportions of any substance other than charcoal and would furnish no therapeutically active amount of any ingredient.

DISPOSITION: June 17, 1947. Pleas of nolo contendere having been entered, the court imposed a fine of \$25 and costs against each defendant.

2190. Misbranding of Far-Vet Merco-Tabs, Far-Vet Gwyo-Dine Tablets, and Far-Vet Gwyo-Spray. U. S. v. Joseph Pogoriler (Farmers Veterinary Supply Co.). Plea of guilty. Fine, \$300. (F. D. C. No. 20104. Sample Nos. 18345-H to 18347-H, incl.)

INFORMATION FILED: July 17, 1946, District of Minnesota, against Joseph Pogoriler, trading as the Farmers Veterinary Supply Co., St. Paul, Minn.

ALLEGED SHIPMENT: Between the approximate dates of December 20, 1944, and March 16, 1945, from the State of Minnesota into the State of South Dakota. A number of leaflets entitled "Dealers' Price List 1944," which accompanied the article, were shipped during the fall of 1944 from the State of Minnesota into the State of South Dakota.

PRODUCT: Analyses showed that the *Far-Vet Merco-Tabs* contained approximately 8 grains of mercuric chloride per tablet; that the *Far-Vet Gwyo-Dine Tablets* consisted essentially of potassium dichromate, potassium guaiacol sulfonate, sodium chloride, iodine, and creosote; and that the *Far-Vet Gwyo-Spray* was a liquid containing camphoraceous substances, phenol, thymol, iodine and turpentine in an inert oil base.

NATURE OF CHARGE: *Far-Vet Merco-Tabs*. Misbranding, Section 502 (a), the statements on the label, "For Drinking Water Medication * * * Dissolve 1 tablet in 1 gallon of drinking water. In aggravated cases, use 2 tablets to 1 gallon of water. Allow no other water. At the first sign of an outbreak— isolate all infected birds in separate pen or house to avoid spreading the disease among the rest of the flock. Begin treatment immediately, continuing for about a week and repeating thereafter as indicated," and the statement in the circular, "For Fowl Cholera, Typhoid and Coccidiosis," were false and misleading. These statements represented, suggested, and implied that the article would be an adequate treatment for cholera, typhoid, and coccidiosis in fowls, whereas it would not be an adequate treatment for those conditions.

Far-Vet Gwyo-Dine Tablets. Misbranding, Section 502 (a), the statements on the label, "Poultry Solution Tablets * * * Dissolve 1 tablet in 1 gallon of drinking water. Change water daily," and the statements in the circular, "For Roup, Colds, and all Respiratory ailments," were false and misleading. These statements represented, suggested, and implied that the article when used as directed would be effective in the treatment of roup, colds, and all respiratory ailments of poultry, whereas it would not be effective for those purposes.

Far-Vet Gwyo-Spray. Misbranding, Section 502 (a), the statements on the label, "Spray Application For Poultry * * * Fill atomizer or spray gun with undiluted Gwyo-Spray and spray nostrils, around the eyes and down the throat of birds. Birds should then be placed in separate pen or house to avoid contact with healthy birds," and the statement in the circular, "Spray Inhalant For Roup, Colds and Brooder Pneumonia," were false and misleading. These statements represented, suggested, and implied that the article would be effective in the treatment of roup, colds, and brooder pneumonia in poultry, whereas it would not be effective for those purposes.

DISPOSITION: November 26, 1946. A plea of guilty having been entered, the defendant was fined \$300.

2191. Misbranding of Jaques' Poultry Preparation, Jaques' Worm Powder, Jaques' B C R, and Jaques' Inhalant Spray. U. S. v. Frank M. Jaques (F. M. Jaques Co.). Plea of guilty. Fine, \$400. (F. D. C. No. 20167. Sample Nos. 18678-H, 19188-H to 19190-H, incl.)

INFORMATION FILED: On or about June 11, 1947, Western District of Wisconsin, against Frank M. Jaques, trading as the F. M. Jaques Company, La Crosse, Wis.

ALLEGED SHIPMENT: On or about May 28 and 31 and June 14, 1945, from the State of Wisconsin into the State of Minnesota.

PRODUCT: Analyses disclosed that the *Jaques' Poultry Preparation* was a solution containing essentially potassium chloride, magnesium sulfate, potassium dichromate, and small amounts of nitrate, but containing no chlorates; that the *Jaques' Worm Powder* was a reddish-colored powder containing essentially plant material, including 32.76 percent ether extract (kamala resins) and 2.82 percent nicotine, but containing no nux vomica alkaloids; that the *Jaques' B C R* was an aqueous solution containing essentially potassium dichromate, potassium chlorate, tarry material, and a very small amount of aromatic camphoraceous oils; and that the *Jaques' Inhalant Spray* was an aqueous solution of formaldehyde and glycerin containing a small amount of aromatic camphoraceous oils.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the products and in circulars entitled "Information for Treating Poultry With Jaques' Remedies" which accompanied the *Jaques' Poultry Preparation*, the *Jaques' BCR*, and the *Jaques' Inhalant Spray* were false and misleading. These statements represented, suggested, and created the impression that the *Jaques' Poultry Preparation* when used as directed would be effective to treat bowel conditions of poultry and would be effective as a poultry regulator and conditioner; that the *Jaques' Worm Powder* when used as directed would be effective to remove round worms and ascarides from poultry; that the *Jaques' BCR* when used as directed would be effective in the treatment and prevention of respiratory diseases of poultry; and that the *Jaques' Inhalant Spray* when used as directed would be effective in the prevention and treatment of respiratory diseases of poultry and hogs. The articles would not be effective for the purposes claimed. The statement "Active Ingredients * * * Potassium Chlorate" borne on the label of the *Jaques' Poultry Preparation* and the statement "A Combination of * * * Nux Vomica Active Ingredients * * * Nux Vomica" borne on the label of the *Jaques' Worm Powder* were false and misleading since the former contained no potassium chlorate and the latter contained no nux vomica.

DISPOSITION: June 18, 1947. A plea of guilty having been entered, the court imposed a fine of \$100 on each of the 4 counts of the information.

2192. Misbranding of Occoton and Gemocco. U. S. v. Earl Rhine (Oelwein Chemical Co.). Plea of guilty. Fine, \$450 and costs. (F. D. C. No. 21440. Sample Nos. 19644-H, 50737-H, 51057-H.)

INFORMATION FILED: April 22, 1947, Northern District of Iowa, against Earl Rhine, trading as the Oelwein Chemical Co., Oelwein, Iowa.

ALLEGED SHIPMENT: On or about November 20, 1945, and February 23 and March 25, 1946, from the State of Iowa into the State of Minnesota.

PRODUCT: Analyses disclosed that the *Gemocco* was an aqueous solution containing water, potassium permanganate, aluminum sulfate, salt, and a small amount of potassium chlorate and hydrochloric acid; that a portion of the *Occoton* was an alkaline aqueous solution containing compounds of copper, sodium, ammonium, sulfate, and carbonate, together with capsicum; and that the remainder of the *Occoton* was an alkaline solution containing water, copper sulfate, sodium sulfate, sodium carbonate, and ammonium hydroxide, together with aromatic substances.

NATURE OF CHARGE: *Occoton*. Misbranding, Section 502 (a), certain statements on the label of the article, in a circular entitled "Feed the Occo Way," and in a book known as an "Instruction Book," accompanying the article, were false and misleading since they represented and suggested that the article would be efficacious as an alkalinizer and alkaline astringent for hogs, poultry, and baby chicks; that it would be efficacious in the cure, mitigation, treatment, and prevention of simple anemia in hogs, poultry, and baby chicks, due to copper

deficiency; that when used with soaked oats it would act as a broom sweeping through the intestinal tract and remove the mucous membrane; that its ingredients possessed an antiseptic power which would check and heal necrotic areas; that it would work through the blood stream and intestines; that it possessed a double action; that it would be effective in the prevention of all diseases, ailments, and abnormal conditions of swine; that it would be efficacious in the cure, mitigation, treatment, and prevention of necro; and that it would be efficacious to prevent an anemic tendency in suckling pigs and necrotic conditions in the new pig crop. The article would not be efficacious for the purposes represented.

Gemocco. Misbranding, Section 502 (a), the statement "Recommended as an antiseptic to be added to drinking water," the name "Gemocco," and the statements containing directions for use displayed upon the label of the article were false and misleading since the name and statements represented and suggested that the article when used as directed would be effective as an internal antiseptic and germicide. The article would not be effective for such purposes.

DISPOSITION: April 22, 1947. A plea of guilty having been entered, the court imposed a fine of \$150, plus costs, on each of the 3 counts of the information.

2193. Misbranding of Remrow Water Wormer and Guardex. U. S. v. **Liberty Oil Company, Inc.** Plea of guilty. Fine, \$55 and costs. (F. D. C. No. 21449. Sample Nos. 21600-H, 51046-H, 66801-H.)

INFORMATION FILED: February 6, 1947, Southern District of Iowa, against the Liberty Oil Company, Inc., Des Moines, Iowa.

ALLEGED SHIPMENT: On or about September 9, 1945, and February 6 and 15, 1946, from the State of Iowa into the States of Nebraska and Minnesota.

PRODUCT: Analysis showed that the *Remrow Water Wormer* was an aqueous solution containing iron, sodium, sulfates, carbonates, calcium, magnesium, potassium, manganese, chloride, and phosphates, but containing no phenothiazine; and that the *Guardex* consisted of an alkaline aqueous suspension of salts of iron, calcium, sodium, magnesium, sulfate, and carbonate, with traces of phosphates, chlorides, potassium, and manganese, but containing no phenothiazine.

LABEL, IN PART: "Remrow Water Wormer," or "Guardex."

NATURE OF CHARGE: *Remrow Water Wormer.* Misbranding, Section 502 (a), the following statements on the jug label were false and misleading: "Remrow (Spell it backwards, it spells Wormer) Water Wormer Watch Results For Hogs, Cattle, Sheep, Horses, Poultry and pet Stock. To aid in the removal of Large Round Worms * * * Important: Be sure that livestock and poultry receive no other water while treatment is under way. Do not expect to see whole worms expelled. Action of Water Wormer instead tends to help disintegrate worms and worm eggs in the system. You should see improvement in appetite, assimilation and appearance. If patients tend to become re-infected, repeat treatment in 45 to 60 days when and if needed. Do not feed milk or buttermilk while treating * * * [Directions given for treatment of pigs, cattle, sheep, horses, other livestock, and poultry]." The statements represented, suggested, and created in the mind of the reader the impression that the article would be effective in the removal of worms and worm eggs from hogs, cattle, sheep, horses, goats, poultry, and pet stock, whereas it would not be effective for such purposes.

Guardex. Misbranding, Section 502 (a), the following statements on the jug label were false and misleading: "Guardex for hogs, Cattle, Sheep, Horses and Poultry Indicated in the Removal of Large Round Worms * * * [Directions for treatment of pigs, sheep, hogs, horses, cattle, and poultry] IMPORTANT: Do not expect to see worms. You should see improvements in appetite, assimilation and appearance before six days are completed. Guardex tends to help disintegrate worms and worm eggs in animal system." The statements represented, suggested, and created in the mind of the reader the impression that the article would be effective in the removal of large round worms from hogs, cattle, sheep, horses, and poultry, whereas it would not be effective for such purposes.

DISPOSITION: April 28, 1947. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$55, plus costs.

2194. Misbranding of Blake's Mineral Compound. U. S. v. 12 Packages * * *. (F. D. C. No. 21244. Sample No. 72725-H.)

LIBEL FILED: October 31, 1946, District of Wyoming.

ALLEGED SHIPMENT: On or about July 5, 1946, by the Hy-Life Mineral Co., from Denver, Colo.

PRODUCT: 12 3½-pound packages of *Blake's Mineral Compound* at Wheatland, Wyo. Analysis indicated that the product consisted essentially of approximately 21.27 percent each of ammonium chloride, sodium sulfate, potassium chlorate, and calcium carbonate, about 4 percent of iron oxide, and 10 percent of tobacco powder, and a small amount of oil of anise. A number of circulars entitled "Thousands This Year Again Will Never Reach Market," which had been delivered to the consignee at Wheatland by a salesman of the shipper, were displayed with the product.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling represented and suggested that the article when used as directed would be effective in the prevention of bloating of livestock, whereas the article when used as directed would not be effective for that purpose.

DISPOSITION: On November 19, 1946, the Hy-Life Mineral Co. having accepted service and consented to the entry of a decree, and the court having found that the product was misbranded, judgment of condemnation was entered and the product was ordered destroyed. On November 21, 1946, the decree was amended to reserve to the claimant, the Hy-Life Mineral Co., the right to post bond and to receive the product for the purpose of relabeling in the manner provided by law.

2195. Misbranding of Ideal Livestock and Poultry Liquid. U. S. v. 20 Cans * * *. (F. D. C. No. 22192. Sample No. 67181-H.)

LIBEL FILED: January 23, 1947, District of Nebraska.

ALLEGED SHIPMENT: On or about November 20, 1946, by the Ideal Products Co., from Belle Plaine, Iowa, to Sioux City, Iowa, and subsequently transported from Sioux City to Lyons, Nebr., by L. S. Oathout.

PRODUCT: 20 5-gallon cans of *Ideal Livestock and Poultry Liquid* at Lyons, Nebr. Analysis showed that the article consisted essentially of a dark brown liquid containing plant extractives, probably cascara sagrada, licorice root, and gentian root, together with creosote and alkali and reducing sugars.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain label statements appearing in the circular accompanying the article were false and misleading. These statements represented and suggested that the article would be effective in the treatment of flu in hogs, roup in poultry, and shipping fever in cattle; that it would be effective for feeding, for dairy-cattle with poor appetite, and for unthrifty and poorly doing animals, due to coughing and scouring; that it would be effective for animals showing rough hair and bad skin and running a temperature and for sows that might be slinking off; that it would be effective to aid vitality and to improve the breeding of both male and female hogs; that it would be effective in the treatment of cattle showing loss of appetite, dark urine, diarrhea, or constipation, and in the treatment of unthrifty chicks and poultry that were not doing well or were badly out of condition. The article would not be effective for such purposes.

DISPOSITION: March 4, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2196. Misbranding of Early Bird worm medicine. U. S. v. 9 Bottles * * *. (F. D. C. No. 22690. Sample No. 74014-H.)

LIBEL FILED: March 12, 1947, District of Massachusetts.

ALLEGED SHIPMENT: On or about February 15, 1947, by Huard Laboratories, from Norwich, Conn.

PRODUCT: 9 1-ounce bottles of *Early Bird worm medicine* at South Sudbury, Mass., together with 50 circulars entitled "Stepping Ahead in Worm Therapy." Analysis disclosed that the product consisted essentially of male fern, arecoline hydrobromide, thymol, santonin, podophyllin, fluid extract of senna, and castor oil.

LABEL, IN PART: "Early Bird Improved For All Types of Worm Infection."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the above-mentioned circulars were false and misleading since they represented and suggested that the article would be effective in the removal of all types and species of worms which infest dogs. The article would not be effective for such purposes, but would be capable only of effectively expelling tape worms from dogs.

DISPOSITION: July 15, 1947. Default decree of condemnation and destruction.

2197. Misbranding of Sponge-Away. U. S. v. 820 Bottles * * *. (F. D. C. No. 22701. Sample Nos. 44383-H, 44384-H, 44500-H.)

LIBEL FILED: March 17, 1947, Southern District of California.

ALLEGED SHIPMENT: On or about March 21, July 30, and September 20, 1946, by William Cooper & Nephews, Inc., from Chicago, Ill.

PRODUCT: 820 1-ounce bottles, 89 3-ounce bottles, and 15 8-ounce bottles of *Sponge-Away* at Huntington Park, Calif., together with 141 pamphlets entitled, "Dog Owner's Digest," 420 leaflets entitled, "Danger Stop His Scratching," and 7 cardboard counter display stands. Analysis showed that the product consisted chiefly of a terpene-bearing oil, sulfonated oil, water, and rotenone.

LABEL, IN PART: "A PULVEX Quality Dog Product Sponge-Away Kills Fleas, Lice, and Ticks Controls Summer Eczema."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and designs in the labeling of the article were false and misleading since they represented and suggested that the article would be an effective treatment of summer eczema of dogs, whereas it would not be an effective treatment for this condition.

DISPOSITION: June 10, 1947. William Cooper & Nephews, Inc., claimant, having requested the removal of the case, an order was entered on April 3, 1947, directing that the case be removed for trial to the Southern District of Illinois. Following such removal, the claimant failed to file an answer to the libel, and on June 10, 1947, he was found to be in default. Judgment of condemnation was entered and the product was ordered destroyed.

2198. Misbranding of W. B. A. Poultry Tonic. U. S. v. 11 Pails and 3 Cartons * * *. (F. D. C. No. 22199. Sample Nos. 67739-H, 67740-H.)

LIBEL FILED: January 24, 1947, District of Kansas.

ALLEGED SHIPMENT: On or about September 30, 1946, by the Western Buyers Association, from Kansas City, Mo.

PRODUCT: 11 25-pound pails and 3 5-pound cartons of *W. B. A. Poultry Tonic* at Newton, Kans. Analysis showed that the produce consisted essentially of a red, powdered mixture containing iron oxide, sodium chloride, calcium and sodium carbonates, magnesium sulfate (epsom salt), copper sulfate, charcoal, and a small amount of plant material, indicating tobacco and nux vomica.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Poultry Tonic * * * 100% Active Ingredients" and "Poultry Tonic to be used as an aid in the prevention of diseases * * * 100% active ingredients" were false and misleading since they represented and suggested that the article would be effective as a poultry tonic and as an aid in the prevention of disease, and that all ingredients of the article were present in therapeutically active amounts. The article was not effective as a poultry tonic or as an aid in the prevention of disease, and the ingredients declared were not present in therapeutically active amounts.

Further misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents.

DISPOSITION: May 13, 1947. Default decree of condemnation and destruction.

DRUG ACTIONABLE BECAUSE OF OMISSION OF, OR UNSATISFACTORY, INGREDIENTS STATEMENTS*

2199. Misbranding of Ramol (mineral oil). U. S. v. 4 1-Barrel Lots * * *. (F. D. C. Nos. 22403 to 22406, incl. Sample Nos. 53930-H to 53933-H, incl.)

LIBELS FILED: January 22, 1947, Northern District of Ohio.

*See also Nos. 2167, 2169, 2178.

ALLEGED SHIPMENT: September 15 and 20 and October 19 and 26, 1946, by B. Ostroff, from Pittsburgh, Pa.

PRODUCT: 4 55-gallon barrels of *Ramol* at Cleveland, Ohio. Analysis showed that the product was United States Pharmacopoeia Mineral Oil.

LABEL, IN PART: "Ramol 350 Oil U. S. P."

NATURE OF CHARGE: Misbranding, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug, mineral oil.

DISPOSITION: March 6 and April 1, 1947. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

DRUG ACTIONABLE BECAUSE OF FAILURE TO BEAR AN ACCURATE STATEMENT OF THE QUANTITY OF THE CONTENTS*

2200. Misbranding of Sulfa-Tyro-Cide. U. S. v. Oliver W. Nelson (Nelson Laboratories). Plea of guilty. Fine, \$50. (F. D. C. No. 21462. Sample No. 51522-H.)

INFORMATION FILED: April 16, 1947, District of South Dakota, against Oliver W. Nelson, trading as Nelson Laboratories, at Sioux Falls, S. Dak.

ALLEGED SHIPMENT: On or about April 29, 1946, from the State of South Dakota into the State of Minnesota.

PRODUCT: Analysis showed that the product contained sulfanilamide, sulfathiazole, and ammonium chloride.

LABEL, IN PART: "Sulfa-Tyro-Cide."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the article failed to bear a label containing the place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), the label failed to contain an accurate statement of the quantity of the contents since the bottle label contained no statement of the quantity of the contents.

DISPOSITION: April 30, 1947. The defendant having entered a plea of guilty, the court imposed a fine of \$50.

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Estrogenic substances-----	2169		

*See also No. 2198.

¹ (2171) Prosecution contested.

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¹ (2171) Prosecution contested.



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NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2201-2250

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

OSCAR R. EWING, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., January 6, 1948.

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DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2201. Misbranding of seconal sodium pulvules. U. S. v. Dayton B. Blaine and Claude C. Schwab. Pleas of guilty. Defendants fined \$500 and \$100, respectively. (F. D. C. No. 21453. Sample Nos. 24032-H, 49052-H, 49162-H.)

INFORMATION FILED: March 11, 1947, Northern District of Texas, against Dayton B. Blaine and Claude C. Schwab, president and manager, respectively, of the Red Cross Pharmacy, Inc., Dallas, Tex.

INTERSTATE SHIPMENT: Between the approximate dates of January 14 and 30, 1946, from Indianapolis, Ind.

LABEL, IN PART (When shipped): "Pulverized Seconal Sodium 1½ Grs. (0.1 Gm.) (Sodium Propyl-methyl-carbinyi Allyl Barbiturate, Lilly) * * * Caution—to be dispensed only by or on the prescription of a physician."

NATURE OF CHARGE: That on or about April 3, 4, and 7, 1946, while a number of capsules of the drug were being held for sale after shipment in interstate commerce, the defendants caused to be removed a number of the capsules from the bottle in which they were shipped, caused to be repacked the aforesaid capsules into envelopes which were unlabeled except for the figure "12" which appeared on several of the envelopes, and caused to be sold these capsules without a prescription.

The information charged further that the acts of the defendants resulted in the misbranding of the drug in the following respects: Section 502 (d), the drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit-forming, and the label

*For presence of a habit-forming narcotic without warning statement, see No. 2201; omission of, or unsatisfactory, ingredients statements, Nos. 2223, 2234, 2240, 2243; failure to comply with the packaging requirements of an official compendium, No. 2214; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2221, 2232, 2234, 2240, 2243; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2240; cosmetics, subject to the drug provisions of the Act, Nos. 2230-2234.

of the drug in the envelopes failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement, "Warning—May be habit-forming"; Section 502 (f) (1), the envelopes containing the drug bore no labeling containing directions for use; and, Section 502 (f) (2), they bore no labeling containing warnings against use of the drug in those pathological conditions, or by children, where its use may be dangerous to health, or against unsafe dosage and methods and duration of administration.

DISPOSITION: March 11, 1947. Pleas of guilty having been entered, the court imposed fines of \$500 and \$100, respectively, against defendants Blaine and Schwab.

2202. Misbranding of Nanette Hormone Cream. U. S. v. 274 Jars, etc. (F. D. C. No. 22989. Sample Nos. 61334-H to 61336-H, incl.)

LIBLE FILED: April 25, 1947, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 8 and 21, 1947, by the Nix Cosmetics Co., Inc., from Memphis, Tenn.

PRODUCT: 274 2-ounce jars and 16 6-ounce jars of *Nanette Hormone Cream* at Pittsburgh, Pa. Analysis indicated that the product had essentially the composition stated on its label.

LABEL, IN PART: "Nanette Hormone Cream Each 2 Ozs. Contains 5 Mgs. Stilbestrol (Synthetic Estrogenic Substance)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Hormone Cream" and the label statement "Each 2 Ozs. Contain 5 Mgs. Stilbestrol (Synthetic Estrogenic Substance)" were false and misleading since they represented and suggested that the article contained a hormone and that it would exert a beneficial hormone-like effect, or beneficial estrogenic effect, upon the body when used as directed, whereas the article did not contain a hormone and would produce no beneficial hormone-like effect, or beneficial estrogenic effect, when used as directed.

Further misbranding, Section 502 (f) (1), the directions for use in the labeling "Apply gently one-half heaping teaspoonful at bedtime. Leave on overnight." were inadequate since they failed to indicate the conditions in which the article was to be used, the body area to which the article was to be applied, and the duration of its use.

DISPOSITION: May 20, 1947. Default decree of condemnation and destruction.

2203. Misbranding of calcium polysulphide solution. U. S. v. 5 Drums * * *. (F. D. C. No. 23499. Sample Nos. 68292-H, 68293-H, 86127-H.)

LIBLE FILED: July 14, 1947, District of Kansas.

ALLEGED SHIPMENT: On or about February 26 and 27, 1947, by the Sulphur Products Co., Inc., from Greensburg, Pa.

PRODUCT: 5 drums of *calcium polysulphide solution* at Sabetha, Kans. The shipper supplied the consignee with a suggested form of label containing directions for use, but had not entered into any agreement with the consignee relative to the labeling of the article, as contemplated by Section 503 (a), to the effect that the article would not be adulterated or misbranded when relabeled.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: September 24, 1947. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2204. Adulteration Bethiamin, Livitamin, and calcium gluconate. U. S. v. The S. E. Massengill Company. Plea of guilty. Fine, \$3,000. (F. D. C. No. 20204. Sample Nos. 7678-H, 20850-H, 21738-H, 21757-H.)

INFORMATION FILED: February 3, 1947, Eastern District of Tennessee, against The S. E. Massengill Co., a corporation, Bristol, Tenn.

ALLEGED SHIPMENT: On or about December 15, 1944, and November 1 and December 8, 1945, from the State of Tennessee into the States of Missouri and New York.

LABEL, IN PART: "Bethiamin A Brand of Thiamine Hydrochloride (B₁) * * * For Intramuscular or Intravenous Administration," "Calcium Gluconate, 10%," or "Livitamin Represents in one Fluid Ounce * * * Thiamine Hydrochloride (B₁) 3 mg. in 100 cc. 10.14."

NATURE OF CHARGE: *Bethiamin.* Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance by reason of the presence of viable mold; and, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, in that it purported and was represented to be suitable and appropriate for intramuscular and intravenous administration, a use which requires a sterile product, whereas the article was unsuitable and inappropriate for intramuscular and intravenous administration since it was unsterile by reason of contamination with viable mold.

Calcium gluconate. Adulteration, Section 501 (d), boric acid had been substituted in part for "Calcium Gluconate Ampuls," in that the article purported to be and was represented as "Calcium Gluconate Ampuls," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and the article contained boric acid, whereas "Calcium Gluconate Ampuls," the specifications of which are set forth in the Pharmacopoeia, do not contain boric acid.

Livitamin. Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, in that it was represented to contain 3 milligrams of thiamine hydrochloride in 1 fluid ounce and 10.14 milligrams of thiamine hydrochloride in 100 cc., whereas it contained less thiamine hydrochloride than represented.

DISPOSITION: March 4, 1947. A plea of guilty having been entered, the court imposed a fine of \$1,000 on each of the 3 counts of the information.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2205. Adulteration and misbranding of estrogenic hormones. U. S. v. Organics, Inc., and Lawrence Hicks. Plea of guilty on behalf of corporation; plea of not guilty by individual defendant. Fine of \$500 and costs against corporation; individual defendant found not guilty. (F. D. C. No. 22009. Sample Nos. 15452-H, 52460-H.)

INFORMATION FILED: April 8, 1947, Northern District of Illinois, against Organics, Inc., Chicago, Ill., and Lawrence Hicks, president of the corporation.

ALLEGED SHIPMENT: On or about May 29 and July 8, 1946, from the State of Illinois into the States of Ohio and Michigan.

PRODUCT: Examination showed that the product contained 60 percent of the labeled claim for estrogenic activity, or 6,000 International Units per cubic centimeter.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, in that it purported and was represented to possess a physiological activity equivalent to 10,000 International Estrone Units per cubic centimeter, whereas it possessed a physiological activity equivalent to less than 10,000 International Estrone Units per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Natural Estrogenic Hormones Isolated from Gravid Equine Urine consisting principally of Estrone * * * 10,000 I. U. per cc." was false and misleading.

DISPOSITION: June 24, 1947. A plea of guilty having been entered on behalf of the corporation, and a plea of not guilty having been entered by the individual, the court imposed a fine of \$500 and costs against the corporation and found the individual defendant not guilty.

2206. Adulteration and misbranding of P-Drine Sulfathiazole, Elixir Feotone, Sulfedol, isotonic solution ephedrine gluconate, and isotonic ephedrine solution. U. S. v. Benjamin Volk (Summit Pharmaceutical Co.). Plea of guilty. Fine, \$50. (F. D. C. No. 21469. Sample Nos. 3270-H, 15790-H, 43282-H to 43284-H, incl.)

INFORMATION FILED: On or about May 20, 1947, District of New Jersey, against Benjamin Volk, trading as the Summit Pharmaceutical Co., at Morristown, N. J.

*See also No. 2204; veterinary preparations, Nos. 2241, 2242.

ALLEGED SHIPMENT: On or about February 3 and 6, 1946, from the State of New Jersey into the States of Maryland and Michigan.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they purported and were represented to possess, in that there was less ephedrine hydrochloride in the *P-Drine Sulfathiazole*, less alcohol and ferrous sulfate in the *Elixir Feotone*, less desoxyephedrine hydrochloride in the *Sulfedol*, and less ephedrine alkaloid in the *isotonic solution ephedrine gluconate* and the *isotonic ephedrine solution* than the respective articles were represented to contain.

Misbranding, Section 502 (a), the following label statements were false and misleading: (*P-Drine Sulfathiazole*) "Ephedrine Hydrochloride 1 Percent," (*Elixir Feotone*) "Each fluid ounce contains Alcohol 5%, Ferrous Sulphate—20 Grains," (*Sulfedol*) "Desoxyephedrine Hydrochloride 0.125%," and (*isotonic solution ephedrine gluconate* and *isotonic ephedrine solution*) "Contains Ephedrine Alkaloid 1%."

DISPOSITION: June 6, 1947. A plea of guilty having been entered, the court imposed a fine of \$5 on each of the 10 counts of the information.

2207. Adulteration of thiamine hydrochloride tablets. U. S. v. Rexall Drug Co. (United-Rexall Drug Co.). Plea of nolo contendere Fine, \$1,500 (F. D. C. No. 23279. Sample Nos. 62901-H, 62902-H, 81514-H.)

INFORMATION FILED: August 12, 1947, Eastern District of Missouri, against the Rexall Drug Co., a corporation, formerly trading as United-Rexall Drug Co., St. Louis, Mo.

ALLEGED SHIPMENT: Between the approximate dates of November 7, 1945, and June 21, 1946, from the State of Missouri into the States of California and Oregon.

LABEL, IN PART: "Thiamine Hydrochloride (Vitamin B₁) United Drug Co. Boston—St. Louis."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality fell below the official standard since it contained glass.

DISPOSITION: September 29, 1947. A plea of nolo contendere having been entered, the court imposed a fine of \$500 on each of the 3 counts of the information.

2208. Adulteration of physiological salt solution. U. S. v. 178 Vials * * *. (F. D. C. No. 23501. Sample No. 87813-H.)

LIBEL FILED: July 17, 1947, District of New Jersey.

ALLEGED SHIPMENT: On or about June 12, 1947, by the Gotham Pharmaceutical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 178 vials of *physiological salt solution* at Hoboken, N. J.

LABEL, IN PART: "100 cc. Size Sterile Physiological Salt Solution * * * Parenteral."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Physiological Salt Solution for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: September 9, 1947. Default decree of condemnation and destruction.

2209. Adulteration of epinephrine hydrochloride injection. U. S. v. 120 Vials * * *. (F. D. C. 23691. Sample No. 66340-H.)

LIBEL FILED: September 9, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 18, 1947, by Lederle Laboratories Division, American Cyanamide Co. (Shipment made from Pearl River, N. Y.)

PRODUCT: 120 1-ounce vials of *epinephrine hydrochloride injection* at Norristown, Pa.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Epinephrine Hydrochloride Injection," a drug the

name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: October 13, 1947. Default decree of condemnation and destruction.

2210. Adulteration of water for injection. U. S. v. 2,476 Vials * * *. (F. D. C. No. 22743. Sample No. 66307-H.)

LIBEL FILED: March 27, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about January 14 and February 1 and 19, 1947, by Vitamin Corporation of America, from Newark, N. J.

PRODUCT: 2,476 100-cc. vials of *water for injection* at Philadelphia, Pa.

LABEL, IN PART: "Water for Injection or Parenteral Use as a Vehicle or Diluent."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth in that compendium since the article was contaminated with undissolved material.

DISPOSITION: April 22, 1947. No claimant having appeared, judgment of condemnation was entered. It was ordered that the product be destroyed and that the glass vials and rubber stoppers be retained by the shipper after the destruction of the contents.

2211. Adulteration and misbranding of urginin tablets. U. S. v. 25 Bottles, etc. (F. D. C. No. 23162. Sample No. 83102-H.)

LIBEL FILED: June 2, 1947, Western District of Kentucky.

ALLEGED SHIPMENT: On or about March 3, 1947, by the Grisard Laboratories, Inc., from Winchester, Tenn.

PRODUCT: 25 bottles and 26 bottles, each bottle containing 100 tablets, of *urginin tablets* at Louisville, Ky.

LABEL, IN PART: (Bottle) "Urginin, Contains two of the cardio-active glycosides of squill * * * Standardized by the U. S. P. XII Cat Method, Each Tablet * * * equivalent to 2.5 Cat Units. * * * Assayed Biologically"; (circular) Standardized by the physical method of optical rotation; by chemical analysis; and by biological assay using the cat method of Hatcher and Brody."

NATURE OF CHARGE: Adulteration, Section 501 (b), the strength of the article differed from that which it was represented to possess, in that each tablet was represented to be equivalent to 2.5 cat units, whereas when subjected to bio-assay, each tablet was found to possess not more than 1.55 cat units per tablet, or not over 62 percent of the strength declared on the label.

Misbranding, Section 502 (a), the label statement "Standardized by the U. S. P. XII Cat Method" was misleading. The statement suggested, implied, and created the impression that the article is recognized in the United States Pharmacopoeia, Twelfth Revision, whereas it is not recognized in the Pharmacopoeia.

DISPOSITION: August 29, 1947. Default decree of condemnation and destruction.

2212. Adulteration of burdock root. U. S. v. 14 Bags * * *. (F. D. C. No. 22512. Sample No. 81409-H.)

LIBEL FILED: February 11, 1947, District of Oregon.

ALLEGED SHIPMENT: On or about October 22, 1946, by Dan S. Carroll, from Vernal, Utah.

PRODUCT: 14 bags, containing approximately 404 pounds, of *burdock root* at Portland, Oreg.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Burdock Root," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since it was moldy.

DISPOSITION: April 11, 1947. Default decree of condemnation and destruction.

2213. Adulteration and misbranding of gauze bandage. U. S. v. 34 Cartons, etc.
(F. D. C. No. 22202. Sample Nos. 44670-H, 44671-H.)

LIBEL FILED: January 27, 1947, District of Arizona.

ALLEGED SHIPMENT: On or about November 15, 1946, by the Hampton Mfg. Co., from Carlstadt, N. J.

PRODUCT: 34 cartons and 20 cartons, each carton containing 12 packages, of *gauze bandage*, at Phoenix, Ariz.

LABEL, IN PART: "Blue Cross * * * Gauze Bandage Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Gauze Bandage," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading as applied to an article that was not sterile.

DISPOSITION: June 12, 1947. Default decree of condemnation and destruction.

2214. Adulteration and misbranding of adhesive dressings. U. S. v. 1,449 Boxes * * *. (F. D. C. No. 21087. Sample Nos. 1653-H to 1656-H, incl.)

LIBEL FILED: September 30, 1946, Middle District of North Carolina.

ALLEGED SHIPMENT: Between the approximate dates of March 27 and June 17, 1946, by Smith and Nephew, Inc., from New York, N. Y.

PRODUCT: 1,449 boxes of *adhesive dressings* at Lexington, N. C.

LABEL, IN PART: "Adhesive Band-O-Plast Wound Dressings," or "Band-O-Plast First Aid Outfit No. 1 * * * Elastic Antiseptic Adhesive Dressings."

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the official standard since they were not sterile.

Misbranding, Section 502 (a), the statement "Wound Dressings" on the label of one of the products was false and misleading since the statement represented and suggested that the product would be suitable for use on wounds, whereas it was not suitable for use on wounds since it was contaminated with living micro-organisms. The statements "Antiseptic" and "Apply the antiseptic gauze pads to the wound" on the label of the other product were false and misleading since the product was not antiseptic.

Further misbranding, Section 502 (g), neither product was packaged and labeled as prescribed in the United States Pharmacopoeia, which provides that "Each adhesive absorbent gauze is packaged individually in such manner that sterility is maintained until the individual package is opened. One or more individual packages are packed in a second protective container" and "The label shall bear a statement that compress is colored, but the coloring agent does not render the gauze antiseptic."

DISPOSITION: December 9, 1946. Smith and Nephew, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

2215. Adulteration and misbranding of prophylactics. U. S. v. 81 Gross * * *. (F. D. C. No. 22916. Sample No. 90626-H.)

LIBEL FILED: April 10, 1947, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about September 30, 1946, by the Allied Latex Corp., from East Newark, N. J.

PRODUCT: 81 gross of *prophylactics* at Norfolk, Va. Examination of 288 samples showed that 4.2 percent were defective in that they contained holes.

LABEL, IN PART: "Gems Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: May 15, 1947. Default decree of condemnation and destruction.

2216. Adulteration and misbranding of prophylactics. U. S. v. 64 Gross * * *.
 (F. D. C. No. 23012. Sample No. 91426-H.)

LIBEL FILED: May 19, 1947, District of Colorado.

ALLEGED SHIPMENT: On or about September 10, 1946, by International Distributors, from Memphis, Tenn.

PRODUCT: 64 gross of *prophylactics* at Denver, Colo. Examination of samples showed that the article was defective in that it contained holes.

LABEL, IN PART: "Xcello's Prophylactics Mfd. by the Killian Mfg. Co., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: July 15, 1947. Default decree of condemnation and destruction.

2217. Adulteration and misbranding of prophylactics. U. S. v. 32 Gross, etc
 (F. D. C. Nos. 22740, 23455. Sample Nos. 66607-H, 90769-H.)

LIBELS FILED: March 28 and June 23, 1947, District of Columbia and Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 13 and April 14, 1947, by World Merchandise Exchange, Inc., from New York, N. Y.

PRODUCT: *Prophylactics*. 23½ gross at Washington, D. C., and 32 gross at Philadelphia, Pa. Examination of samples from each lot showed that 4 percent from the Philadelphia lot and 6 percent from the Washington lot were defective in that they contained holes.

LABEL, IN PART: "Tetratex Prophylactics [or "Texide Rubber Sheaths"] Manufactured by L. E. Shunk Latex Products, Inc. Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the statements "Prophylactics" and "Prophylactics Tested" borne on the label of the article in the Philadelphia lot were false and misleading as applied to an article containing holes.

DISPOSITION: July 8 and August 6, 1947. Default decrees of condemnation and destruction.

2218. Adulteration and misbranding of prophylactics. U. S. v. 50 Gross * * *.
 (F. D. C. No. 22861. Sample No. 61043-H.)

LIBEL FILED: April 22, 1947, Western District of New York.

ALLEGED SHIPMENT: On or about March 28, 1947, by the Schaeffer Products Co., from Cleveland, Ohio.

PRODUCT: 50 gross of *prophylactics* at Rochester, N. Y. Examination of 288 samples showed that 2.4 percent were defective in that they contained holes.

LABEL, IN PART: "La Vita Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactics * * * aid in the prevention of disease" were false and misleading as applied to an article containing holes.

DISPOSITION: May 26, 1947. Default decree of condemnation and destruction.

2219. Adulteration and misbranding of prophylactics. U. S. v. 37 Gross * * *.
 (F. D. C. No. 23006. Sample No. 76229-H.)

LIBEL FILED: May 6, 1947, Northern District of Texas.

ALLEGED SHIPMENT: Between the approximate dates of January 15 and March 13, 1947, by Frank G. Karg, Chicago, Ill.

PRODUCT: 37 gross of *prophylactics* at Dallas, Tex.

LABEL, IN PART: "Pall Mall Aquapac."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "For the protection against the communication of disease" was false and misleading as applied to an article containing holes.

DISPOSITION: June 16, 1947. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

2220. Adulteration and misbranding of Lactobacillus acidophilus culture. U. S. v. Kovac Laboratories, Inc., and Hugh H. von Kleist. Pleas of nolo contendere. Fines of \$150 against the corporation and \$300 against the individual. (F. D. C. No. 23275. Sample Nos. 59460-H, 59462-H, 59463-H.)

INFORMATION FILED: July 21, 1947, Southern District of California, against Kovac Laboratories, Inc., Los Angeles, Calif., and Hugh H. von Kleist, president of the corporation.

ALLEGED SHIPMENT: On or about July 20 and 29 and August 16, 1946, from the State of California into the State of Washington.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Culture Lactobacillus Acidophilus A condensed culture" was false and misleading since it represented and suggested that the article contained significant numbers of *Bacillus acidophilus* organisms, whereas it did not contain significant numbers of *Bacillus acidophilus* organisms, but did contain large numbers of streptococci.

DISPOSITION: August 11, 1947. Pleas of nolo contendere having been entered, the court imposed fines of \$150 against the corporation and \$300 against the individual.

2221. Misbranding of Laken's 9 Drops Capsules and Liquid. U. S. v. Harry Laken (Marshall Drug Co.). Plea of nolo contendere. Fine, \$400. (F. D. C. No. 20202. Sample Nos. 4771-H, 4888-H.)

INFORMATION FILED: December 10, 1946, Eastern District of Pennsylvania, against Harry Laken, trading as the Marshall Drug Co., Philadelphia, Pa.

ALLEGED SHIPMENT: On or about September 5 and October 26, 1945, from the State of Pennsylvania into the State of New Jersey.

PRODUCT: Analysis disclosed that the capsules contained a mixture consisting essentially of aspirin, acetophenetidin, and caffeine, and that the liquid consisted essentially of a water solution of sodium, salicylate, potassium, iodide, and traces of alkaloids.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and the design of a man in pain appearing in circulars entitled "Facts Everyone Should Know About," enclosed with the articles, were false and misleading since they represented and suggested that the articles when used alone or in conjunction with each other would be effective in the treatment of rheumatism, arthritis, backache, swollen joints, lumbago, neuritis, rheumatic pains, and stiff joints; that the liquid would be effective as an analgesic to get at the main cause of so-called rheumatism; and that the capsules would be effective in the treatment of suffering and discomfort associated with common colds. The articles would not be effective for such purposes.

Further misbranding, Section 502 (b) (2), the bottles containing the liquid bore no label containing a statement of the quantity of the contents.

DISPOSITION: June 17, 1947. A plea of nolo contendere having been entered, the court imposed a fine of \$400.

2222. Misbranding of Luebert's Iron Tonic Tablets. U. S. v. A. Gustave Luebert. Plea of nolo contendere. Fine, \$50. (F. D. C. No. 23215. Sample No. 4640-H.)

INFORMATION FILED: August 12, 1947, Eastern District of Pennsylvania, against A. Gustave Luebert, Coatesville, Pa.

ALLEGED SHIPMENT: On or about February 23, 1946, from the State of Pennsylvania into the State of Delaware.

PRODUCT: Analysis disclosed that each tablet of the product contained approximately 1 grain of ferrous carbonate with manganese, a phosphide, and a laxative plant drug.

LABEL, IN PART: "Luebert's (Nox 'em Brand) Iron Tonic Compound Tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in a circular entitled "Luebert's Remedies," shipped

*See also Nos. 2202, 2205, 2206, 2211, 2213-2219.

with the article, were false and misleading. These statements represented and suggested that the article would be effective to restore one's appetite; that it would assist nutritive functions and promote activity and nutrition of the nerves and muscles; that it was a general tonic to the digestive tract; that it would assist in the assimilation of food; that it would furnish rich red blood; that it was essential to good health, sound nerves, and normal vitality; that it would build up new vim and vigor in one's body; that it would be efficacious in the treatment of weak, tired nerves; that it was a valuable digestive and tonic medicine; that it would give more strength and vigor to the entire system; that it would be of value to one in a weak and rundown condition; that it would help one to put himself in better condition; and that it would be valuable in helping the nervous system. The article would not be effective for such purposes.

DISPOSITION: October 1, 1947. A plea of nolo contendere having been entered, the court imposed a fine of \$50.

2223. Adulteration of Glancaps Special Formula Capsules. U. S. v. 46 Boxes * * *. (F. D. C. No. 23437. Sample No. 88156-H.)

LIBEL FILED: August 28, 1947, Southern District of Ohio.

ALLEGED SHIPMENT: Delivered on or about July 15, 1947, by Mr. Darnell of the Darnell Drug Co., Indianapolis, Ind.

PRODUCT: 46 boxes, each containing 40 capsules, of *Glancaps Special Formula* at Cincinnati, Ohio. The label stated that the article contained 3 minimis of oil of albasantal, 2 minimis of oleoresin cubeb, 3 minimis of oil of copaiba, 2 minimis of rectified oil of terpen, and 5 grains of extract of zea mays.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label designation "Glancaps" and the label statements "Glancaps are compounded from only the purest vegetable oils and extracts, especially for the relief of enlarged prostate glands, kidney, bladder and urinary irritations, and are healing and cleansing to the entire urinary system * * * extreme cases may require two or more treatments for complete elimination of urinary poisons" were false and misleading since the article was not an adequate treatment for diseases of the glands and would not fulfill the promises of benefits stated and implied; and, Section 502 (e) (2), the article was fabricated from 2 or more ingredients, and its label failed to bear the common or usual name of each active ingredient since oil of albasantal, rectified oil of terpen, and extract of zea mays are not the common or usual names of oil of santal, rectified oil of turpentine, and extract of corn silk, respectively.

DISPOSITION: October 3, 1947. Default decree of destruction.

2224. Adulteration and misbranding of Calbrite Calcium-Phosphorus Tablets and misbranding of Bextra Vitamin B₁ Tablets, Hi-Plex Vitamin Tablets, Organic Iron Tablets, and Ritamine Vitamin and Mineral Capsules. U. S. v. 354 Bottles, etc. (and a quantity of booklets, leaflets, and placards). (F. D. C. No. 21013. Sample Nos. 59448-H to 59450-H, incl., 59452-H to 59454-H, incl.)

LIBEL FILED: October 15, 1946, Western District of Washington.

ALLEGED SHIPMENT: The products were shipped between the approximate dates of November 14, 1945, and June 25, 1946, by the American Diet aids Co., from Los Angeles, Calif., and Yonkers, N. Y. The booklets were shipped on or about August 17 and 28, 1945, and April 6, 1946, from Watertown, Mass., and the leaflets and placards were shipped during 1944 and 1945 from Yonkers, N. Y., by the same firm.

PRODUCT: 4 bottles of *Bextra Vitamin B₁ Tablets*, 354 bottles of *Calbrite Calcium-Phosphorus Tablets*, 234 bottles of *Hi-Plex Vitamin B Complex Tablets*, 207 bottles of *Organic Iron Tablets*, 481 packages of *Ritamine Vitamin & Mineral Capsules*, and a number of booklets entitled "Health Topics Contains important articles on Health Foods, Diet, Nutrition" and (other booklets) "Health Topics * * * Get Ready to Live Longer," a quantity of leaflets entitled "Are 50 Million People Taking Vitamins Blindfold?" and "Catalog and Price List," and several placards entitled "Vitamins Their relation to poor nutrition and susceptibility to Colds Sinusitis," "This Box of Ritamine," "Good News for Folks over 40," and "Positively Prevent the Dangers of all known Vitamin Deficiencies."

Examination of a sample of the *Calbrite Calcium-Phosphorus Tablets* showed that 6 tablets supplied less than 450 U. S. P. units of Vitamin D. Partial examination of a sample of the *Ritamine Vitamin & Mineral Capsules* and some of the other items indicated that they contained the ingredients listed upon their labels.

LABEL, IN PART: "Bextra Extra Strength Vitamin B₁ Tablets 1000 International Units Vitamin B₁ per tablet or 3 mg. Thiamin," "Calbrite Calcium-Phosphorus Tablets with Vitamin D * * * 6 Calbrite tablets supply: Calcium 1260 mgs., Phosphorus 900 mgs., Vitamin D 900 U. S. P. Units 225% daily minimum requirements. * * * Each Calbrite tablet supplies 210 mgs. calcium, 150 mgs. phosphorus, 150 U. S. P. Units Vitamin D," "Triple Strength Hi-Plex Vitamin B Complex Special High Potency Yeast and added factors of Vitamin B Complex Each Tablet contains: Vitamin B₁—1500 U. S. P. (or Intl.) Units Vitamin B₂—2 Mg. (2000 micrograms) Niacin—5 Mg. (5,000 micrograms) Copper—0.6 Milligrams d-Calcium Panthenate—1 Mg. (1000 micrograms) Plus all the other natural Vitamin B Complex factors found in four leading sources—brewer's yeast, wheat germ, rice bran extract and processed corn extract * * *," "Enrich With Liver Extract Special high potency organic Iron Tablets together with Liver Extract and additional components of the Vitamin B Complex," "Ritamine Vitamin & Mineral Capsules * * * Two small Ritamine capsules contain all the vitamins known to be needed in the diet, plus important essential minerals."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling were misleading. These statements represented, suggested, and created in the mind of the reader the impression that the articles would be effective to accomplish the following purposes, whereas they would not be effective for such purposes and would not be capable of fulfilling the promises of benefits stated and implied:

That the *Bextra Vitamin B₁ Tablets* would keep one fit and keep the nerves working normally, sharpen the appetite, maintain proper digestion, prevent and cure easy tiring, jittery and other subnormal conditions, stimulate the appetite and assimilation, prevent interference with children's growth, prevent lack of appetite, constipation, nervousness, irritability, heart disturbances, decreased energy, and polyneuritis, give tone to the stomach and intestines, protect against the effects of alcohol, and favorably influence conditions affecting the nerves, the digestive tract, and the normal health functions of the human body.

That the *Calbrite Calcium-Phosphorus Tablets* would prevent tooth decay, nervousness, muscular weakness, bone deformities, poor development, and weak arches; that it would help keep one fit and strong; that it would constitute a helping hand to provide a keener, more vigorous state of physical fitness; that it would enable adults to maintain higher levels of vitality; and that 6 of the tablets contained 900 U. S. P. units of vitamin D, provided 225 percent of the minimum daily requirements of vitamin D, and were the equivalent of more than a quart of milk. Six of the tablets did not contain 900 U. S. P. units of vitamin D, would not provide 225 percent of the minimum daily requirements for that vitamin, and were not the equivalent of more than a quart of milk.

That the *Hi-Plex Vitamin B Complex Tablets* would be effective to keep one fit and keep the nerves working normally; to sharpen the appetite; to maintain proper digestion; to prevent and cure easy tiring, jittery, and other subnormal conditions; to stimulate the appetite and assimilation; to prevent and cure constipation, nervousness, irritability, heart disturbances, decreased energy, and polyneuritis; to give tone to the stomach and intestines; to protect against polyneuritis and the effects of alcohol; to prevent and cure failure to grow, intestinal degenerative diseases, colitis, skin eruptions, sore tongue, mouth ulcers, mental symptoms, and abnormalities of the skin and hair; to protect against eye degeneration and cataract; to favorably influence conditions affecting the nerves, the digestive tract, and the normal health functions of the human body; to provide new zest for living, good health, and vitality; to transform food into energy; to make or keep one mentally alert; to improve one's health, vigor, and appearance; to correct tiredness, peplessness, and inability to get things done; to favorably affect digestion, the nervous system, and mental and physical alertness; that it would be particularly beneficial for people over 35 or 40 years of age; that it would produce effects different from those produced by ordinary B Complex vitamins; that if taken regularly for 2 months, it would cause the user to begin to feel new sparkle, new energy, and

new zest; and that it would be useful in the treatment of diabetes, resulting in the reduction of the insulin requirement or the elimination of the need for insulin.

That the *Organic Iron Tablets* would be effective to give women pep and vitality, energy, and radiant health; to attract and hold men, and thus acquire happiness, romance, love, and attention; to make possible rich red blood, providing the energy and pep that men admire; to overcome thin, weak, watery blood that makes it difficult for women and girls to keep up with other women; to remedy pale cheeks, pale lips, tiredness, headaches, and other depressing conditions; to constitute a helping hand; to provide a keener, more vigorous state of physical fitness; and to produce the therapeutic effects of liver extract.

That the *Ritamine Vitamin & Mineral Capsules* would increase life span, promote tooth development, make possible pregnancy and lactation, promote a healthy condition of the skin, prevent and correct intestinal disorders, retarded growth, lowered vitality, dry skin, and severe eye diseases and inflammation, effect normal functioning of the nerves, stimulate appetite and assimilation, burn up acids of tiredness, prevent and correct interference with children's growth, prevent lack of appetite, constipation, nervousness, irritability, heart disturbances, decreased energy, and polyneuritis, give "tone" to the stomach, intestines, and capillary blood vessels, protect against polyneuritis and the effects of alcohol, prevent ulcers and tooth decay, effect proper use of food minerals, prevent and remedy bleeding gums, joint pains, tiredness, physical weakness, anemia, swollen limbs, muscular weakness, bone deformities, poor development, calcium starvation symptoms, failure to grow, intestinal degenerative diseases, colitis, skin eruptions, sore tongue, mouth ulcers, mental symptoms, and abnormalities of the skin and hair, prevent skin diseases, prolong the active life span, protect against eye degeneration and cataract, favorably influence conditions affecting the nerves, the digestive tract, and the normal health functions of the human body, help make possible buoyant health, prevent people looking and feeling older than they are, losing energy, strength, and buoyant health, becoming physically older than their actual age, tiring easily, and suffering unwarranted aches and pains, and prevent loss of normal strength by the skin and eyesight; that it would be effective against hay fever and would prevent the shortcomings of age, poor teeth, eating habits, or diet from holding one back; that 2 tablets daily would insure an adequate mineral intake, compensate for partial or total mineral deficiency in the diet, and constitute "mineral insurance"; that it would be an antidote for improper nourishment, resulting in lowered vitality, low blood pressure, and simple anemia; that it would maintain the strength of the walls of the blood vessels; that it would have a special value for middle-aged and elderly people; that it would prevent or correct deficiencies evidenced by loss of energy, lack of buoyant health, little "zip," and failing strength; that it would increase one's capacity to work; that the combination of ingredients of the article represented the solution of a problem by research chemists; that it was a "wonder of modern science"; that it would effect fullest health and vigor and constitute a helping hand to provide a keener, more vigorous state of physical fitness; that it was the "right combination" of vitamins and minerals for people generally; that it constituted a remedy for colds, sinusitis, and sore throat; that it would provide all the important vitamins and minerals found in hundreds of pounds of fresh vegetables, fresh fruits, milk, and other foods; and that it was the nutritional equivalent of milk, lamb, eggs, apples, and butter.

It was alleged also that the articles were misbranded and that, in addition, the *Calbrite Calcium-Phosphorus Tablets* was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: December 31, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

2225. Misbranding of Major B Complex Tablets. U. S. v. 80 Dozen Cartons, etc.
(F. D. C. No. 22932. Sample Nos. 74516-H to 74518-H, incl.)

LIBEL FILED: April 15, 1947, District of New Hampshire.

ALLEGED SHIPMENT: On or about February 16 and March 16, 1943, and April 1, 1944, by Major Vitamins, Inc., from New York, N. Y.

PRODUCT: *Major B Complex Tablets*. 80 dozen cartons, each containing 24 tablets; 47 so-called "deals," each consisting of 6 100-tablet bottles; and

6 cartons, each containing 48 tablets, 6 cartons, each containing 24 tablets, and 44 dozen cartons, each containing 1 bottle of 100 tablets, at Keene, N. H.
LABEL, IN PART: "Major-B Brand Natural Vitamin B Complex with added Thiamine."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and designs in the circulars entitled "Buoyant Health for All the Family" and "How Vitamins Bring Health and Vigor to All the Family," enclosed with the article, were false and misleading since they represented and suggested that the article would be effective to provide greater energy, steadier nerves, better digestion, improved health and vigor, better appetite, insurance from vitamin deficiencies, physical well-being, and protection against frequent colds, constipation, fatigue, digestive upsets, and other common ills; that the article would provide the vitamins found in whole-wheat bread, eggs, milk, liver, and tomato juice; that there are widespread dietary deficiencies which would be corrected by use of the article; that the article contained nutritionally significant amounts of all vitamins of the B-complex; that foods are an unreliable source of vitamins, and, therefore, it is desirable, if not necessary, to supplement the ordinary diet with the article. The article would not be effective for the purposes represented; it would not provide the vitamins found in whole-wheat bread, eggs, milk, liver, and tomato juice; there are not widespread dietary deficiencies that would be corrected by use of the article; and the article did not contain nutritionally significant amounts of all vitamins of the B-complex. Furthermore, foods are a reliable source of vitamins, and it is not desirable or necessary to supplement the ordinary diet with the article.

DISPOSITION: August 19, 1947. Default decree of condemnation and destruction.

2226. Misbranding of L'Vito Peptrons. U. S. v. 357 Bottles * * *. (F. D. C. No. 23202. Sample No. 68396-H.)

LIBEL FILED: June 19, 1947, Western District of Oklahoma.

ALLEGED SHIPMENT: On or about February 25, 1947, by Oxford Products, Inc., from Cleveland, Ohio.

PRODUCT: 357 75-tablet bottles of *L'Vito Peptrons* at Oklahoma City, Okla. Examination showed that the product contained approximately 3.8 milligrams of iron per tablet.

LABEL, IN PART: "L'Vito Peptrons 75 Tablets Contents: Iron Peptonized Haemoglobin Reduced Iron Natural Vitamin B Complex from Yeast Calcium Pantothenate Niacin Dehydrated Whole Yeast And Added Vitamin B₁ (Thiamin chloride) B₂, B₆ * * * Directions Adults: Take one or two tablets three or four times a day one hour before meals and at bed-time * * * A General Tonic supplying a supplementary source of Vitamin B₁ and Peptonized Haemoglobin Reduced Iron."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "L'Vito Peptrons" was misleading since it suggested that the article would stimulate the vital processes and contribute to the pep and vitality of the user, whereas the article would not accomplish those benefits.

Further misbranding, Section 502 (a), the label statement "A General Tonic" was misleading since the article when consumed as directed would not be effective as a tonic.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: July 21, 1947. Default decree of condemnation and destruction.

2227. Misbranding of Palmer's Bi-Sal Tablets, Grabill's Tablets, and Hite's Inco-Tablets. U. S. v. 289 Bottles, etc. (F. D. C. No. 23627. Sample Nos. 76378-H to 76380-H, incl.).

LIBEL FILED: On or about August 8, 1947, Northern District of Texas.

ALLEGED SHIPMENT: On or about February 12 and April 11, 1947, by the Allied Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 160 100-tablet bottles and 129 50-tablet bottles of *Palmer's Bi-Sal Tablets*, 65 100-tablet bottles and 70 65-tablet bottles of *Grabill's Tablets*, and 67 50-tablet bottles of *Hite's Inco-Tablets* at Dallas, Tex. Examination showed that the *Palmer's Bi-Sal Tablets* contained laxative drugs, including one-half grain of phenolphthalein per tablet; that the *Grabill's Tablets* con-

tained laxative ingredients, including aloin, and a trace of an alkaloid; and that the *Hite's Inco-Tablets* contained, per tablet, 1 grain of theobromine, 0.4 grain of sodium salicylate, and a citrate.

NATURE OF CHARGE: *Palmer's Bi-Sal Tablets*, misbranding, Section 502 (a), the label statement "Recommended as of value in the treatment of Hepatic insufficiency and Intestinal Putrifaction due to lack of Bile" was false and misleading since the article would not be effective in the treatment of such conditions.

Grabill's Tablets, misbranding, Section 502 (a), the label statement "Tonic-Stimulant" was false and misleading since the article would not act as either a tonic or a stimulant.

Hite's Inco-Tablets, misbranding, Section 502 (a), the label statement "A mild urinary antiseptic" was false and misleading since the article was not a mild urinary antiseptic.

DISPOSITION: September 23, 1947. Default decree of condemnation and destruction.

2228. Misbranding of L. G. Urbaton and R. L. D. Precor Tablets. U. S. v. 43 Bottles of L. G. Urbaton, etc. (F. D. C. No. 23628. Sample Nos. 85801-H, 85802-H.)

LIBEL FILED: August 12, 1947, Northern District of West Virginia.

ALLEGED SHIPMENT: Between the approximate dates of July 26, 1946, and April 24, 1947, by the Allied Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 43 bottles of *L. G. Urbaton* and 385 bottles of *R. L. D. Precor Tablets* at Clarksburg, W. Va. The *L. G. Urbaton* was in 16- and 32-fluid-ounce size bottles, and the *R. L. D. Precor Tablets* was in 20-, 50-, 75-, and 200-tablet size bottles. Examination showed that the *L. G. Urbaton* contained per tablespoonful (one-half fluid ounce) 2.1 grains of sodium salicylate, 0.5 grain of iron peptonate, and a laxative drug; and that the *R. L. D. Precor Tablets* contained theobromine and sodium salicylate, 2.72 grains, and potassium citrate, 0.85 grain, per tablet.

NATURE OF CHARGE: *L. G. Urbaton*, misbranding, Section 502 (a), the label statement "For the temporary relief of Distress and Discomfort due to Pain of Rheumatism" was false and misleading since the article would not be effective in the treatment of such condition.

R. L. D. Precor Tablets, misbranding, Section 502 (a), the label statement "A mild urinary antiseptic" was false and misleading since the article was not a mild urinary antiseptic.

DISPOSITION: September 19, 1947. Default decree of condemnation and destruction.

2229. Misbranding of Syntenon Capsules. U. S. v. 14 Boxes * * *. (F. D. C. No. 22864. Sample No. 83008-H.)

LIBEL FILED: April 24, 1947, Eastern District of Tennessee.

ALLEGED SHIPMENT: On or about July 17 and September 16, 1946, by the Sumlar Co., from New York, N. Y.

PRODUCT: 14 boxes of *Syntenon Capsules* at Knoxville, Tenn. Analysis indicated that the product possessed the composition stated on its label.

LABEL, IN PART: (Label) "Syntenon 60 Capsules For Mitigating Symptoms of Hay Fever, Asthma and Sinus Distress due to Vitamin C Deficiency Each Capsule Contains Ephedrine Sulphate 0.02 Gm., Vitamin C (Ascorbic Acid) 2,000 U. S. P. Units, with Small Quantities of Calcium Lactate"; (circular) "Vitamin C found to curb hay fever. The bigger the dose up to 1,000 milligrams the more relief, data in report show. 'Distinct gains' and 'great relief' from hay fever in one to three days from relatively large doses of Vitamin C * * * quick and simple relief to thousands of sufferers."

NATURE OF CHARGE: Misbranding, Section 502 (a). The charge recommended by the Federal Security Agency was that the above-quoted statements were false and misleading since hay fever, asthma, and sinus distress are not due to vitamin C deficiency and since the article would not be effective for mitigating sinus distress.

DISPOSITION: June 16, 1947. Default decree of condemnation. On June 24, 1947, the product was ordered destroyed.

2230. Misbranding of Pyrozide Tooth Powder. U. S. v. Web Distributing Co., Inc. Plea of guilty. Fine, \$50. (F. D. C. No. 14289. Sample Nos. 60707-F, 81771-F.)

INFORMATION FILED: December 21, 1945, District of New Jersey, against the Web Distributing Co., Inc., Newark, N. J.

ALLEGED SHIPMENT: On or about January 3 and April 6, 1944, from the State of New Jersey into the State of New York.

PRODUCT: Analysis disclosed that the product consisted essentially of calcium carbonate, magnesium carbonate, borax, soap, small amounts of plant materials, phenolic material, and essential oils.

LABEL, IN PART: "Pyrozide Tooth Powder * * * Sole Manufacturer National Dental Co., Newark, N. J."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. These statements represented and suggested that the article would be efficacious in the maintenance of firm, healthy gums; that it would keep the gums healthy; and that it would be efficacious in the cure, mitigation, treatment, and prevention of pyorrhea, gingivitis, Vincent's angina (trench mouth), and all other diseases of the oral tissue. The articles would not be efficacious for such purposes.

DISPOSITION: June 20, 1947. A plea of guilty having been entered, the court imposed a fine of \$25 on each of the 2 counts of the information.

2231. Misbranding of Chlorydent Tooth Paste. U. S. v. 168 Dozen Tubes * * *. (F. D. C. No. 22735. Sample No. 91040-H.)

LIBEL FILED: March 28, 1947, Southern District of New York.

ALLEGED SHIPMENT: On or about February 25, 1947, by Welco, Inc., from Newark, N. J.

PRODUCT: 168 dozen 2-ounce tubes of *Chlorydent Tooth Paste* at New York, N. Y. Examination showed that the product consisted essentially of calcium phosphate, chlorophyll, water, and flavoring compounds.

LABEL, IN PART: "Chlorydent Green Tooth Paste."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements on the tube label "Chlorydent's active ingredients are recognized by the dental profession as a * * * preventor of bleeding gums and the formation of Tartar" and the statements in the circular enclosed with each tube "The actual function of Chlorophyll is converting Carbon Dioxide and similar disagreeable gases into Oxygen, which of itself is a deodorant and a preventative * * * Chlorydent prevents the formation of Tartar. Chlorydent will aid the healing of bleeding gums" were false and misleading since the article would not prevent or aid in the healing of bleeding gums, prevent the formation of tartar, or convert gases in the mouth into oxygen.

DISPOSITION: April 25, 1947. Default decree of condemnation. Product ordered delivered to a charitable institution.

2232. Misbranding of No Equal Tooth Paste. U. S. v. 123 Tubes * * * and a number of circulars. (F. D. C. No. 22705. Sample No. 39540-H.)

LIBEL FILED: March 24, 1947, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about February 3, 1947, by the No Equal Products Co., from Chicago, Ill. The product was shipped on or about February 3, 1947, and the circulars were received by the consignee on or about February 17, 1947.

PRODUCT: 123 tubes of *No Equal Tooth Paste* at Milwaukee, Wis., together with 150 circulars entitled "No Equal The World's Greatest Tooth Paste." Analysis indicated that the product consisted essentially of bentonite, water, calcium carbonate, and small amounts of fixed oil and methyl salicylate. No statement of the quantity of the contents appeared on the tube label.

LABEL, IN PART: "No Equal Tooth Paste * * * The Great Colloidal Mineral Tooth Paste."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading since they represented and suggested that the article would be effective in the treatment of rheumatic and pulmonary affections, disorders of the scrofulous and eczematous type, abscesses, sores, wounds, toothache, pyorrhea, mouth sores, bleeding gums, abscessed teeth, inflamed

tonsils, sinus trouble, ulcerated and pus cases, dead and abscessed teeth where bone tissue had partly decayed, irritation caused by artificial teeth, tongue blisters, swollen gums, sore throat, catarrh, and disorders of the mouth and throat; that it would be effective for healing and hardening tender and bleeding gums; that it would be effective for stopping toothache, preventing and relieving pyorrheal conditions, and healing sunburn, infection, cuts, bruises, scalds, and insect and animal bites; that it would be effective in healing power, in absorbing poisonous substance of the body, in relieving soreness and inflammation, in correcting and preventing disorders, in preserving the teeth and tissues, in checking ailments and stopping pain, and in relieving pains in the gums of teething infants. The article would not be effective for such purposes.

Further misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents.

DISPOSITION: May 28, 1947. Default decree of condemnation and destruction.

2233. Misbranding of Miracle-Aid, Miracle Cream, Miracle Bath, and Miracle Milk Bath. U. S. v. 438 Bottles of Miracle-Aid, etc. (F. D. C. No. 22694. Sample Nos. 38744-H to 38751-H, incl.)

LIBEL FILED: March 21, 1947, Northern District of Illinois.

ALLEGED SHIPMENT: Between the approximate dates of July 18, 1946, and January 3, 1947, by the American Beauty Products Co., from Dallas, Tex., Salt Lake City, Utah, Minneapolis, Minn., Pittsburgh and Wilkes-Barre, Pa., Milwaukee, Wis., Cleveland, Ohio, and Indianapolis, Ind.

PRODUCT: 438 6-ounce bottles of *Miracle-Aid*, 471 1-pound jars of *Miracle Cream*, 161 6-pound bags of *Miracle Bath*, and 9 6-pound bags of *Miracle Milk Bath* at Chicago, Ill.

Analyses indicated that the *Miracle-Aid* consisted essentially of water, with small proportions of soapy material, gum, and perfume; that the *Miracle Cream* consisted essentially of epsom salt, sodium sulfate, water, fatty acids, and methyl salicylate; that the *Miracle Bath* consisted essentially of epsom salt, sulfur, and soap; and that the *Miracle Milk Bath* consisted essentially of epsom salt and powdered skimmed milk.

NATURE OF CHARGE: Misbranding. Section 502 (a), certain statements in the labeling of the articles were false and misleading. These statements represented and suggested that the *Miracle-Aid* would be effective in the removal of wrinkles and double chin; that the *Miracle Cream* and the *Miracle Milk Bath* would be effective to bring about a reduction in body weight; and that the *Miracle Bath* would be effective to reduce body weight and would be effective in the treatment of rheumatism and arthritis. The articles would not be effective for such purposes.

DISPOSITION: August 15, 1947. Default decree of condemnation and destruction.

2234. Misbranding of Anabelle Antiseptic Manicure Wafers. U. S. v. 25 Boxes * * *. (F. D. C. No. 23205. Sample No. 1576-H.)

LIBEL FILED: On or about July 9, 1947, Southern District of Florida.

ALLEGED SHIPMENT: On or about March 21, 1947, by the Superior Soap Corp., from Brooklyn, N. Y.

PRODUCT: 25 boxes each containing 180 *Anabelle Antiseptic Manicure Wafers* at St. Petersburg, Fla. Examination showed that the product was colored soap.

LABEL, IN PART: "Anabelle Antiseptic Manicure Wafers."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Antiseptic Manicure Wafers," "Guard Against Manicure Infection," and "Antiseptic wafers that help protect against manicure infections" were false and misleading since the product was not antiseptic and would not guard or help protect against manicure infection; Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (e) (2), it was fabricated from 2 or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

DISPOSITION: September 10, 1947. Default decree of condemnation and destruction.

2235. Misbranding of Cloro. U. S. v. 3 Cloro Devices and a number of circulars. Tried to the jury; directed verdict for the Government. (F. D. C. No. 20746. Sample No. 40688-H.)

LIBEL FILED: On or about September 9, 1946, Eastern District of Missouri.

ALLEGED SHIPMENT: The devices were shipped on or about July 25, 1946, from Tucson, Ariz., to St. Louis, Mo., by L. P. Dickey, and the circulars were transported on or about June 30, 1946, by Dr. H. E. Glaesner.

PRODUCT: 3 Cloro devices at St. Louis, Mo., together with a number of circulars entitled "Here's to Your Health * * * L. P. Dickey * * * Tucson, Ariz." Examination showed that the devices were electrical, and that when charged and operated in accordance with the directions furnished, they would give off chlorine gas and vapors of eucalyptol.

LABEL, IN PART: (Sticker on back of device) "Roh Radio Co. 519 North Sixth Avenue, Tucson, Arizona."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned circulars accompanying the devices were false and misleading since they represented and suggested that the devices would be effective in the treatment of sinus, arthritis, hay fever, bronchitis, and common colds, whereas chlorine, whether used alone or in combination with eucalyptol, is not effective in the treatment of sinus, arthritis, hay fever, bronchitis, and common colds.

DISPOSITION: L. P. Dickey appeared as claimant and filed an answer on October 11, 1946, denying that the product *Cloro* was a device within the meaning of the law and, further, that it was misbranded.

The case came on for trial before a jury on February 3, 1947, during which trial testimony was introduced by the claimant and the Government. On February 5, 1947, at the conclusion of the trial, the court directed the jury to return a verdict in favor of the Government, which was done.

On February 7, 1947, judgment of condemnation was entered and the devices were ordered destroyed. On March 14, 1947, the decree was amended, providing for the delivery of the devices for the use of the Food and Drug Administration.

2236. Misbranding of Electreat (device). U. S. v. 3 * * * and a quantity of printed matter. (F. D. C. No. 23177. Sample No. 49770-H.)

LIBEL FILED: June 6, 1947, Northern District of Texas.

ALLEGED SHIPMENT: On or about March 17, 1947, by the Electreat Mfg. Co., from Peoria, Ill.

PRODUCT: 3 devices known as *Electreat*, at Dallas, Tex., together with 3 instruction charts headed "Electreat Instruction Chart" and 34 circulars headed "Do You Want to Improve Your Health," which were enclosed with the devices. Examination showed that each device consisted of dry cells, a small buzzer coil, and attachments intended to supply an electrical shock to the body.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the charts and circulars were false and misleading. These statements represented and suggested that the device was effective to improve health, to control nerves, and to remove dandruff, and, further, that it was effective in the treatment of sciatica, muscular aches, arthritis and paralysis, sinus trouble, earaches, menstrual disturbances, cracked nerves, rheumatism, aches and pains, heart disease, tight muscles, nervous breakdown, prostate trouble, crippled hands, and about all diseases. The device would not be effective for such purposes.

DISPOSITION: July 22, 1947. Default decree of condemnation and destruction.

2237. Misbranding of Exercycles (devices). U. S. v. 47 * * *. (F. D. C. No. 22958. Sample No. 38290-H.)

LIBEL FILED: April 28, 1947, Northern District of Illinois.

ALLEGED SHIPMENT: By the Exercycle Corporation. The *Exercycles* were shipped from Hartford, Conn., between the approximate dates of December 3, 1946, and January 27, 1947, and a number of booklets were shipped during 1946, from New York, N. Y.

PRODUCT: 47 *Exercycles* at Chicago, Ill., together with a number of booklets entitled "Exercycle Exercises," "Keeping Fit," "Health in Action," and "Interesting Exercycle Facts." The *Exercycle* resembled a wheelless bicycle and

was operated by an electric motor to produce motion of the pedals, seat, and handle bars.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklets were false and misleading. These statements represented and suggested that the use of the *Exercycle* as directed would be effective to keep one fit, to correct overweight in various portions of the body, to improve posture, to prevent and correct intestinal, circulatory, and nervous disturbances, to maintain all organs of the body in a healthy state, to change mental attitude, to strengthen bones and joints, to protect against gall bladder disturbances, to relieve backache, dysmenorrhea, arthritis, and myositis, and to overcome muscle weakness resulting from poliomyelitis. The use of the *Exercycle* as directed would not be effective for such purposes.

DISPOSITION: On May 15, 1947, the Exercycle Co. of Chicago, Chicago, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered against the *Exercycles*, and it was ordered that they be released under bond for relabeling under the supervision of the Federal Security Agency.

On June 17, 1947, judgment of condemnation was entered against the booklets entitled "Keeping Fit," "Health in Action," and "Interesting Exercycle Facts," and it was ordered that they be destroyed.

DRUGS FOR VETERINARY USE

2238. Misbranding of Beebe Rispol. U. S. v. Beebe Laboratories, Inc., and Dr. Sivert Eriksen. Pleas of guilty. Fines, \$100 against individual and \$300 against corporation. (F. D. C. No. 21480. Sample No. 19762-H.)

INFORMATION FILED: On or about June 5, 1947, District of Minnesota, against Beebe Laboratories, Inc., St. Paul, Minn., and Dr. Sivert Eriksen, general manager.

ALLEGED SHIPMENT: On or about March 2, 1946, from the State of Minnesota into the State of Iowa. A number of accompanying circulars entitled "Beebe Bull's Eye" were shipped during the month of April 1946.

PRODUCT: Analysis showed that the product was a solution containing essentially canaphoraceous oils, menthol, methyl salicylate, formaldehyde, and soap.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading since they represented and suggested that the article when used as directed would be efficacious in helping to stimulate deep breathing of poultry, and that it would be efficacious in the cure, mitigation, and treatment of colds, bronchitis, pneumonia, air sac infection, and deep-seated conditions of poultry, and calf pneumonia and colds of pigs. The article would not be efficacious for such purposes.

DISPOSITION: September 23, 1947. Pleas of guilty having been entered, the court imposed fines of \$100 against the individual and \$300 against the corporation.

2239. Misbranding of Germ-O-Tone. U. S. v. Dean M. Schlarbaum (Germ-O-Tone Laboratories). Plea of nolo contendere. Fine, \$200. (F. D. C. No. 22023. Sample Nos. 44905-H, 44906-H.)

INFORMATION FILED: April 8, 1947, District of Arizona, against Dean M. Schlarbaum, trading as the Germ-O-Tone Laboratories, at Phoenix, Ariz.

ALLEGED SHIPMENT: During the period from July 17 to August 3, 1946, from the State of Arizona into the State of California.

PRODUCT: Analysis disclosed that the product consisted essentially of an aqueous liquid containing compounds of calcium, sulfur, iodide, and probably nitrate.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the article were false and misleading since they represented, suggested, and created the impression that the article was efficacious in the prevention and removal of intestinal worms in poultry, livestock, and dogs, and of lice, mites, bluebugs, fleas and ticks from all age poultry, livestock, and dogs; that it would be efficacious in the prevention of diarrhea, coccidiosis, and other bowel troubles in baby chicks, pouls, growing and adult poultry, and livestock; and that it would be efficacious in the treatment of distemper in all types of livestock, of sorehead, roup, ear canker, and sore hocks in rabbits, and of sorehead, roup, and chickenpox in poultry. The article was not efficacious in the treatment, prevention, and removal of such conditions.

Further misbranding, Section 502 (a), certain other statements on the labels of the article were false and misleading since they represented and suggested that the article was an antiseptic and germicide and a tonic; that it would be efficacious in stimulating the appetite of poultry and livestock; and that it would be efficacious in causing all poultry to "full feather" and all types of livestock to have smooth, silky coats. The article was not an antiseptic and germicide and was not a tonic, and it would not be efficacious for the purposes suggested.

DISPOSITION: June 16, 1947. A plea of nolo contendere having been entered, the court imposed a fine of \$100 on each of the 2 counts of the information.

2240. Misbranding of Save'm and Va-Po-Spra. U. S. v. Emmett J. Smith (Emmett J. Smith & Daughter). Plea of nolo contendere. Fine, \$150. (F. D. C. No. 15504. Sample Nos. 63347-F, 75745-F, 75746-F.)

INDICTMENT RETURNED: August 14, 1945, Middle District of Tennessee, against Emmett J. Smith, trading under the firm name of Emmett J. Smith & Daughter, Nashville, Tenn.

ALLEGED SHIPMENT: On or about June 5, 1944, from the State of Tennessee into the States of Georgia and New York.

PRODUCT: Analyses disclosed that the *Save'm* was a black aqueous liquid with an aromatic odor, consisting essentially of plant extractives, including a small amount of emodin substances; and that the *Va-Po-Spra* was a light-yellow-colored oil with a bottom layer consisting of a small amount of black liquid which resembled tarry material. A trace of an iodine compound was present. The odor was mixed aromatic, with menthol, guaiacol, and vanillin predominating.

NATURE OF CHARGE: *Save'm*, misbranding, Section 502 (a), certain statements on the label of the article, in an enclosed leaflet bearing headings "Directions for Using Smith's *Save'm*" and "Directions for Using Smith's *Va-Po-Spra*," and in an enclosed circular headed "Emmett J. Smith & Daughter Poultry Farms" and addressed "To the Poultry Breeding Public Everywhere" were false and misleading. These statements represented and suggested that the article, when used alone or in conjunction with *Va-Po-Spra*, would be efficacious in the cure, mitigation, treatment, and prevention of such intestinal and internal ailments of poultry as diarrhea, typhoid, cholera, coccidiosis, blackhead, and similar conditions, indicated by the abbreviation "etc." The article would not be efficacious for such purposes. Further misbranding, Section 502 (a), the name of the article "*Save'm*" was false and misleading since the name was applied to a drug intended to be used in the treatment of disease of poultry and represented and suggested that the article would save poultry from disease and death, whereas the article would not save poultry from disease and death; Section 502 (b) (2), the article bore no label containing a statement of the quantity of the contents; Section 502 (e) (2), it failed to bear a label containing the common or usual name of each active ingredient; and, Section 502 (b) (1), a portion of the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Va-Po-Spra, misbranding, Section 502 (a), certain statements on the label of the article and in the above-described circular and leaflet accompanying the article were false and misleading. These statements represented and suggested that the article, when used alone or in conjunction with *Save'm*, would be efficacious in the cure, mitigation, treatment, and prevention of such respiratory ailments of poultry as pox, sore head, canker, bronchitis, brooder pneumonia, gapes, colds, tracheitis, and roup; that it would be efficacious as a general disinfectant for chickens and turkeys; that it would be efficacious in combating respiratory ailments in man and beast; that it would be efficacious in the treatment of colds, hay fever, and asthma in humans and as a treatment and preventative of distemper and pneumonia in puppies and dogs. The article, whether used alone or in conjunction with *Save'm*, would not be efficacious for such purposes. Further misbranding, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents; and, Section 502 (e) (2), the article failed to bear a label containing the common or usual name of each active ingredient.

DISPOSITION: October 8, 1946. A plea of nolo contendere having been entered, the court imposed a fine of \$50 on each of the 3 counts of the information.

2241. Adulteration of Large Round Worm Rx Powder and misbranding of Korum. U. S. v. 172 Bottles, etc. (and 3 other seizure actions). (F. D. C. Nos. 22700, 22736, 22741, 22966. Sample Nos. 19698-H, 19699-H, 53861-H to 53863-H, incl., 53876-H, 53877-H.)

LIBELS FILED: March 18, 26, and 28 and April 28, 1947, Western District of Kentucky and Northern District of Iowa.

ALLEGED SHIPMENT: Between the approximate dates of December 8, 1945, and February 19, 1947, by the I. D. Russell Co., from Kansas City, Mo.

PRODUCT: 172 bottles of *Korum* and 66 packages of *Large Round Worm Rx Powder* at Henderson, Ky., 64 bottles and 48 bottles of *Korum* at Alta and Spirit Lake, Iowa, respectively, and 342 bottles of *Korum* and 10 packages of *Large Round Worm Rx Powder* at Glasgow, Ky. The *Korum* was contained in 8-ounce, 16-ounce, 32-ounce, $\frac{1}{2}$ -gallon, and 1-gallon bottles, and the *Large Round Worm Rx Powder* was contained in 7-ounce and 14-ounce packages.

LABEL, IN PART: "Korum Contains: Sodium Chlorate, Potassium Dichromate, Salt Petre, Epsom Salts, and Water 90%," or "Russell's Large Round Worm Rx Powder A combination of Nicotine Sulphate 6%, Areca Nuts 12%, Copper Sulphate (Pentahydrate) 50%, Iron Sulphate 7%, Capsicum 6%, Nux Vomica 10% (Strychnine Alkaloid .5 Gr. per Oz.), Aniseed 3%, Kamala 3%, Fullers Earth 3%."

NATURE OF CHARGE: *Large Round Worm Rx Powder*, adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since it was represented to contain 6 percent of nicotine sulfate and 7 percent of iron sulfate, whereas it contained less nicotine sulfate and (portion of article) more iron sulfate than that declared on the label.

Korum, misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article would be effective as a mild astringent for chicks, pullets, layers and breeders, turkeys, and pouls, and that it would be effective in the prevention and treatment of disease conditions of poultry, whereas it would not be effective for such purposes.

DISPOSITION: April 26 and 29 and June 4, 1947. Default decrees of condemnation and destruction.

2242. Adulteration and misbranding of Avi-Caps. U. S. v. 22 Bottles * * *. (F. D. C. No. 22684. Sample No. 52313-H.)

LIBEL FILED: March 11, 1947. District of South Dakota.

ALLEGED SHIPMENT: On or about November 1, 1946, by Central Laboratories, from Bensenville, Ill.

PRODUCT: 22 100-tablet bottles of *Avi-Caps* at Dell Rapids, S. Dak. Analysis showed that each tablet of the product consisted essentially of 0.3 grain of nicotine, 0.46 grain of phenothiazine, copper sulfate, and plant material.

LABEL, IN PART: "Cenlab's Avi-Caps."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since the tablets contained less than the declared amounts of nicotine alkaloids and phenothiazine.

Misbranding, Section 502 (a), the following label statements were false and misleading: "To be used as an aid for the control of large round worms (Ascarids) and cecal worms (Heterakis Gallinae) in poultry. * * * Nicotine Alkaloids 0.8 grain. Phenothiazine Comp. (98.3) 5 gr." The product did not contain the stated amounts of nicotine alkaloids and phenothiazine, and when used as directed, it would not be effective in the control of large round worms and cecal worms in poultry.

DISPOSITION: April 10, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2243. Misbranding of Lax-A-Ton, Diarex, Paralax, Mange Oil, Hog Liquid, and Pine-O-Mist. U. S. v. 4 Bottles, etc. (and 2 other seizure actions). (F. D. C. Nos. 22681, 22682, 22921. Sample Nos. 39527-H, 39528-H, 52086-H, 52087-H, 77003-H to 77008-H, incl.)

LIBELS FILED: March 10 and 15 and April 11, 1947. District of Minnesota. Eastern District of Wisconsin, and Northern District of Iowa.

ALLEGED SHIPMENT: On or about October 22 and 26 and November 8, 1946, by Central Laboratories, from Bensenville, Ill.

PRODUCT: 4 1-quart bottles and 3 1-gallon bottles of *Lax-A-Ton*, 22 7-ounce cans and 2 1-pound cans of *Diarex*, 11 16-ounce cans of *Paralax*, 2 1-gallon jugs of *Mange Oil*, 2 1-gallon jugs of *Hog Liquid*, and 23 8-ounce bottles and 14 1-pint bottles of *Pine-O-Mist* at Fairmont, Minn.; 47 1-pound cans and 46 7-ounce cans of *Diarex* at Sioux Center, Iowa; 22 7-ounce cans and 22 1-pound cans of *Diarex* at Pulaski, Wis.; and a number of display cards entitled "Diarex A Mild Astringent Demulcent for Treatment of Scours," display posters entitled "Diarex To The Rescue Again," and one copy of a wholesale price list.

Analyses indicated that the *Lax-A-Ton* was an aqueous solution containing principally potassium nitrate, potassium chlorate, potassium dichromate, and magnesium sulfate; that the *Diarex* consisted essentially of bismuth subnitrate, subcarbonate, phenyl salicylate, tannic acid, sodium bicarbonate, and calcium and magnesium carbonates; that the *Paralax* consisted essentially of nicotine sulfate, copper and iron sulfates, calcium carbonate, nux vomica, and other plant materials; that the *Mange Oil* consisted essentially of sulfur, phenol, and a lethane in a mineral oil base; that the *Hog Liquid* consisted chiefly of lye, sodium and copper sulfates and chlorides, potassium, and guaiacol; and that the *Pine-O-Mist* consisted essentially of creosote, guaiacol, camphor, oil of eucalyptus, pine oil, soap, isopropyl alcohol, and water.

NATURE OF CHARGE: *Lax-A-Ton*, misbranding, Section 502 (a), certain statements on the label were false and misleading since they represented and suggested that the article possessed laxative and tonic properties and was effective as an intestinal astringent for turkeys and chickens, whereas it was not a laxative or a tonic and was not effective as an intestinal astringent for chickens and turkeys.

Diarex, misbranding, Section 502 (a), certain statements on the label, on the display cards and posters, and in the price list were false and misleading since they represented and suggested that the article would be effective in the prevention and treatment of diarrhea and scours in animals, whereas it would not be effective for such purposes.

Paralax, misbranding, Section 502 (a), certain statements on the label and in the price list were false and misleading, since they represented and suggested that the article possessed laxative properties and had some beneficial effect on paralysis of poultry; that it would be effective in the prevention and treatment of intestinal disturbances of chickens and turkeys; that it would be effective for poor digestion and mycosis; and that it would rebuild the bodies of chickens ravaged by disease. The article was essentially worthless for any purpose. Further misbranding, Section 502 (b) (2), the label failed to bear an accurate statement of the quantity of the contents in terms of weight since the quantity of the contents was stated other than in terms of the largest unit; and, Section 502 (e) (2), the article was fabricated from 2 or more ingredients, and its label failed to bear the name and quantity or proportion of strychnine contained therein.

Mange Oil, misbranding, Section 502 (a), certain statements on the label and in the price list were false and misleading since they represented and suggested that the article would be effective in the prevention and treatment of all types of mange of swine, whereas it would not be effective in the prevention and treatment of all types of mange of swine.

Hog Liquid, misbranding, Section 502 (a), certain statements on the label and in the price list were false and misleading since they represented and suggested that the article would be effective in the prevention, control, and treatment of necrotic enteritis in swine, whereas it would not be effective for such purpose.

Pine-O-Mist, misbranding, Section 502 (a), certain statements on the label and in the price list were false and misleading since they represented and suggested that the article would be effective to prevent and treat serious diseases of the respiratory tract of poultry and that its use internally would be effective to assist in speeding recovery from such respiratory conditions, whereas it would not be effective for such purposes; and, further, the name of the article was misleading since it suggested the name of one but not all of the ingredients contained in the formula. Further misbranding, Section 502 (e) (2), the article was fabricated from 2 or more ingredients, and its label failed to bear a statement of the quantity or proportion of isopropyl alcohol contained in it.

DISPOSITION: April 25, May 14, and June 6, 1947. Default decrees of condemnation and destruction.

2244. Misbranding of Niko Niko-Lene and Gold Medal Niko-Lene. U. S. v. 23 Bottles, etc. (F. D. C. No. 20568. Sample Nos. 35995-H, 35996-H.)

LIBEL FILED: On or about August 2, 1946, Western District of Missouri.

ALLEGED SHIPMENT: On or about June 6, 1946, by Niko Laboratories, from Clay Center, Kans.

PRODUCT: 23 1-pint bottles of *Niko Niko-Lene* and 4 1-quart bottles of *Gold Medal Niko-Lene* at St. Joseph, Mo. Analysis disclosed that the articles consisted essentially of water, with small amounts of sulfates of copper, iron, manganese, aluminum and magnesium, potassium dichromate, and methyl violet.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label designations of the articles, i. e., "Niko Niko-Lene" and "Niko-Lene," were misleading since they suggested and implied that the articles contained nicotine which would be effective in the treatment of large round worms that infest poultry, whereas the articles did not contain nicotine and would not be effective in the treatment of any species of worms which infest poultry. Further misbranding, Section 502 (a), certain statements on the label of the articles were false and misleading since they represented and suggested that the articles would be effective as a flock treatment of diseased conditions of poultry, including those diseased conditions which may cause bloody droppings, and that they would be effective as an intestinal astringent, whereas the articles would not be effective in the treatment of any diseased condition of poultry and would not be effective as an intestinal astringent.

DISPOSITION: March 3, 1947. Niko Laboratories, claimant, having withdrawn its answer to the libel, judgment was entered ordering that the products be destroyed.

2245. Misbranding of Kent-Kaps Garlic Capsules and Kent Pure Garlic Extract. U. S. v. 98 Boxes * * * (and 1 other seizure action). (F. D. C. Nos. 20219, 21007. Sample Nos. 45065-H, 54567-H.)

LIBELS FILED: June 10 and September 24, 1946, Southern District of California and Southern District of Florida.

ALLEGED SHIPMENT: Between the approximate dates of February 6 and March 8, 1946, by Kent Laboratories, Inc., from Wilmette, Ill.

PRODUCT: 98 boxes of *Kent-Kaps Garlic Capsules* at Pasadena, Calif., and 74 bottles of *Kent Pure Garlic Extract* at St. Petersburg, Fla. The *Kent-Kaps Garlic Capsules* consisted of a mixture of castor oil and garlic extract.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels were false and misleading. These statements represented and suggested that the *Kent-Kaps Garlic Capsules* would be an effective treatment and preventive for worm infestation in puppies, cats, foxes, mink, and all pets and game; and that the *Kent Pure Garlic Extract* would be effective as a gastric stimulant to help keep dogs and other animals in a healthier condition, as a treatment for diarrhea, and to reduce worm infestation of dogs, cats, foxes, mink, and other small game. The articles would not be effective for the purposes claimed.

DISPOSITION: September 23 and October 29, 1946. No claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

2246. Misbranding of Foxco Vineland Flock Treatment for Worms. U. S. v. 7 Jugs * * *. (F. D. C. No. 23451. Sample No. 74824-H.)

LIBEL FILED: July 15, 1947, District of New Hampshire.

ALLEGED SHIPMENT: On or about March 11, 1947, by the Fox Co., from Newfield, N. J.

PRODUCT: 7 1-gallon jugs of *Foxco Vineland Flock Treatment for Worms* at Dover, N. H. Analysis showed that the product consisted essentially of a light mineral oil with turpentine.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Flock Treatment for Worms (*Ascaridia Lineata*)" was false and misleading since it

represented and suggested that the article when used as directed would be effective in the flock treatment of worms (*Ascaridia lineata*) which infest poultry, whereas it would not be effective for such purpose.

DISPOSITION: September 2, 1947. Default decree of condemnation and destruction.

2247. Misbranding of Ful-O-Pep Super Greens. U. S. v. 413 Bags * * * and 50 booklets. (F. D. C. No. 21622. Sample No. 52151-H.)

LIBEL FILED: December 24, 1946, District of Minnesota.

ALLEGED SHIPMENT: On or about October 23 and 29, 1946, by the Quaker Oats Co., from Cedar Rapids, Iowa.

PRODUCT: 413 100-pound bags of *Ful-O-Pep Super Greens* at Minneapolis, Minn., together with 50 booklets entitled "Save Feed the Ful-O-Pep Way."

LABEL, IN PART: "GUARANTEED ANALYSIS Crude Protein, not less than 19.00 per cent Crude Fat, not less than 4.50 per cent Crude Fibre, not more than 8.00 per cent CARBOHYDRATES Nitrogen-free Extract, not less than 47.00 percent INGREDIENTS: Oatmeal, Hominy Feed, Wheat Bran, Wheat Standard middlings, Barley Feed, Meat Scraps, Soybean Oil Meal, Fish Meal, Liver Meal, Distillers' Dried Grains with Solubles, D-Activated Animal Sterol (Vitamin D), Dried Milk By-Product, Cane Molasses, Dehydrated Alfalfa Meal, Dehydrated Cereal Grasses (from Wheat, Oats, Rye and Barley), Bone Meal 1%, Iodized Salt, 1%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the booklets were false and misleading since they represented and suggested that the article was effective in the treatment of colds, chickenpox, bronchitis, laryngotracheitis, and round worms in poultry, whereas it was not effective for such purposes.

DISPOSITION: October 27, 1947. The Quaker Oats Company, claimant, having denied that the product was misbranded, but having consented to the entry of a decree in order to avoid the expense of a trial, judgment of condemnation was entered. The product was ordered delivered for the use of a charitable or public institution, and the booklets were ordered destroyed.

2248. Misbranding of Singer's Earth Crust Minerals. U. S. v. 140 Bags * * * and a quantity of printed matter. (F. D. C. No. 15267. Sample No. 23601-H.)

LIBEL FILED: February 12, 1945, Western District of Texas.

ALLEGED SHIPMENT: On or about October 17, 1944, from Barrington, Ill., by the Chain of Lakes Duck Farm.

PRODUCT: 140 100-pound bags of *Singer's Earth Crust Minerals* at Nixon, Tex., together with 4,000 circulars entitled "Singer's Earth Crust Minerals" and a placard headed "Livestock and Poultry Raisers." Analysis showed that the product consisted essentially of soil, sand, and small amounts of plant material, with added calcium carbonate, salt, and a phosphate.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and on the circulars and placard were false and misleading since they represented and suggested that the product would be effective in keeping livestock and poultry healthy; that it would prevent poor digestion, loss of appetite, run-down condition, and diseases in general; that it would be effective in removing any species of worms from the intestines of livestock and poultry; that it would lower mortality; that it would prevent the diseased condition of poultry known as range paralysis; and that its use would save feeding costs. The article would not be effective for such purposes.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: May 9, 1947. E. A. Singer, Barrington, Ill., claimant, having consented to the entry of a decree, judgment was entered ordering that the product be released under bond, conditioned upon the destruction or changing and reprinting of the circulars and placard to conform with the law, under the supervision of the Food and Drug Administration.

2249. Misbranding of Security Special Udder Formula. U. S. v. 140 jars, etc. (F. D. C. No. 22738. Sample No. 44385-H.)

LIBEL FILED: April 1, 1947, Southern District of California.

ALLEGED SHIPMENT: Between the approximate dates of June 4 and November 18, 1946, by the Security Remedies Co., from New York, N. Y.

PRODUCT: 140 1-pint jars, 63 5-pound cans, and 4 25-pound cans of *Security Special Udder Formula* at Artesia, Calif. Analysis showed that the product consisted essentially of petroleum, with small amounts of phenol, eucalyptol, bismuth, and zinc, and traces of aluminum, lead, and ichthammol.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article would be effective in the treatment of swollen and congested udders of livestock, in the treatment of sore, lumpy, and painful udders due to mastitis or garget, and as a penetrating antiseptic healing ointment for sores on udders. The article would not be effective for those purposes.

DISPOSITION: June 24, 1947. The Security Remedies Company, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

2250. Misbranding of Illinois Hog Medicine. U. S. v. 19 Sacks * * *. (F. D. C. No. 20261. Sample No. 52946-H.)

LIBEL FILED: July 9, 1946, Southern District of Indiana.

ALLEGED SHIPMENT: On or about May 13, 1946, by the Illinois Mfg. Co., from Quincy, Ill.

PRODUCT: 19 100-pound sacks of *Illinois Hog Medicine*, at Hagerstown, Ind. Analysis showed that the article was a powder consisting essentially of sulfates, carbonates, and bicarbonates; phosphates of calcium, copper, iron, and sodium; and charcoal, fish liver oil, and plant extractive material. The total calcium content was 5.88 percent. Iodine, Chenopodium (American wormseed), and oil of chenopodium were not present in detectable amounts.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling were false and misleading as applied to a product which did not contain the declared amount of calcium, which contained no detectable amounts of American wormseed, oil of chenopodium, or iodine, and which was not an effective hog medicine for all the conditions and diseases which would cause hogs to appear to be not doing well: (Tag) "Hog Medicine * * * Calcium (Ca), not less than 7%." Ingredients: American Worm Seed * * * Oil of Chenopodium * * * Iodine Minimum .02%; (circular) "Hog Medicine * * * When hogs do not appear to be doing well we recommend the following force feed treatment * * * Use 4 pounds of Illinois Hog Medicine for each 2000 pounds of hogs."

DISPOSITION: September 26, 1946. No claimant having appeared, judgment was entered ordering the product delivered to public institutions, for use as hog feed.

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¹ (2235) Seizure contested.

² (2205) Prosecution contested.

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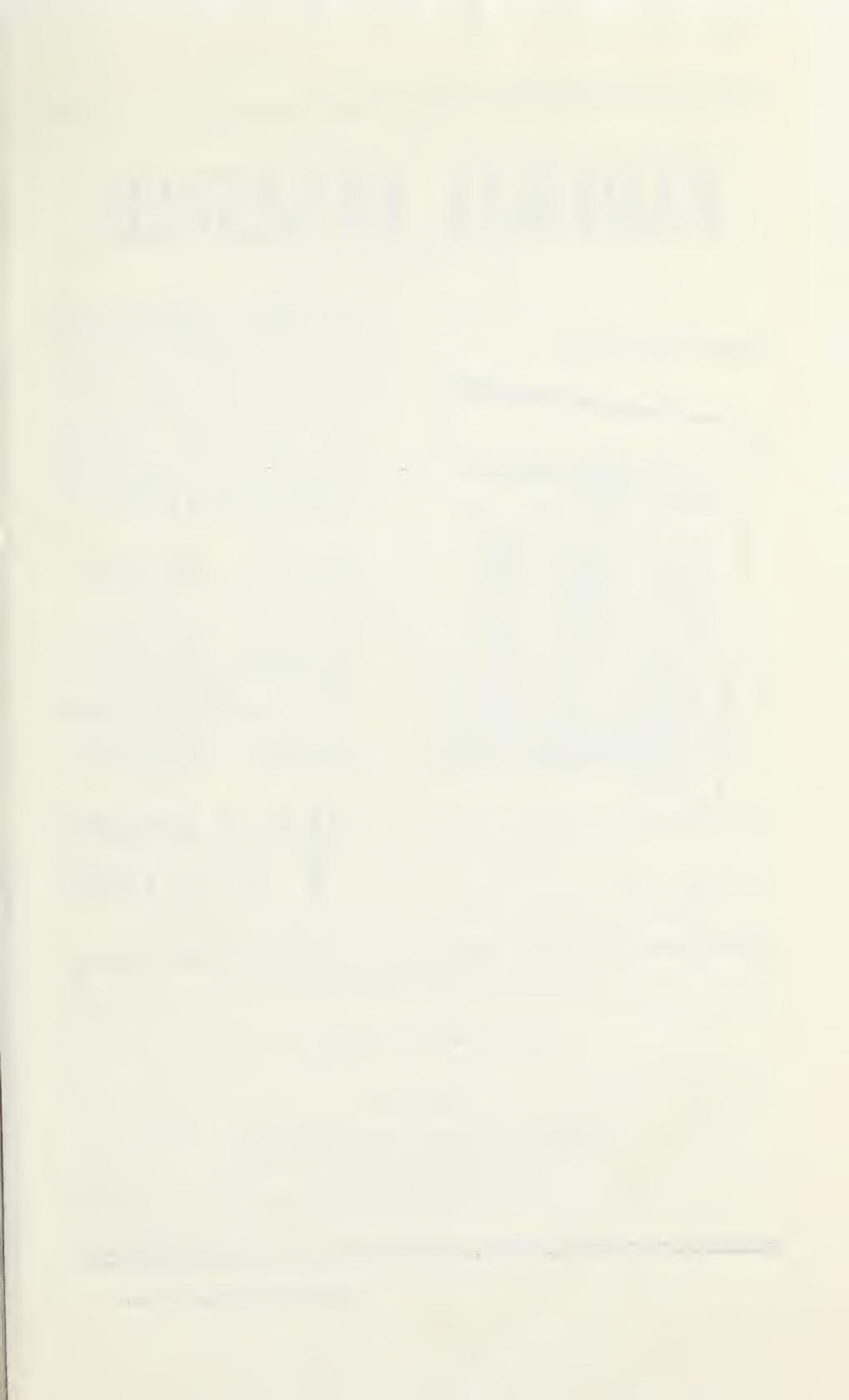
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¹ (2235) Seizure contested.² (2205) Prosecution contested.

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¹ (2235) Seizure contested.² (2205) Prosecution contested.



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FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2251-2300

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

OSCAR R. EWING, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., May 26, 1948.

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DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2251. Misbranding of sulfathiazole tablets, thyroid tablets, seconal pulvules, and nembutal capsules. U. S. v. Carl P. Fletcher. Plea of guilty. Fine, \$200. (F. D. C. No. 21456. Sample Nos. 40445-H to 40447-H, incl., 40453-H.)

INFORMATION FILED: March 31, 1947, Eastern District of Missouri, against Carl P. Fletcher, manager of the Ellis Drug Store, Clayton, Mo.

INTERSTATE SHIPMENT: Between the approximate dates of April 11, 1945, and January 20, 1946, from Indianapolis, Ind., New York, N. Y., and Chicago, Ill., to St. Louis, Mo., of quantities of *sulfathiazole tablets, thyroid tablets, seconal pulvules, and nembutal capsules.*

LABEL, WHEN SHIPPED: "Tablets Sulfathiazole * * * 0.5 Gm. (7.72 grs.) * * * Eli Lilly & Company Indianapolis," "Pulvules Seconal Sodium 1½ grs. (0.1 Gm.) * * * Eli Lilly and Company Indianapolis," "1 Gr. Thyroid Tablets U. S. P. * * * Supreme Pharmaceutical Co. Distributors New York City, N. Y." or "Capsules Nembutal (Pentobarbital Sodium, Abbott) * * * 1½ Grs. * * * Abbott Laboratories North Chicago, Ill."

* For presence of a habit-forming narcotic without warning statement, see No. 2251; failure to comply with the packaging requirements of an official compendium, No. 2273; deceptive packaging, No. 2284.

ALLEGED VIOLATION: On or about July 19, 22, 25, and 26, 1946, while the drugs were being held for sale after shipment in interstate commerce, the defendant removed portions of the drugs from the bottles and boxes in which they had been shipped, repacked them in boxes, and sold them to various persons without a prescription, which acts of the defendant resulted in the drugs being misbranded. The repackaged *sulfathiazole tablets* were labeled "Sulfathiazole"; the repackaged *thyroid tablets* were labeled in part "1 before meal twice daily Ellis Drug Store"; the repackaged *seconal pulvules* were labeled in part "(1) at Bed time Ellis Drug Store"; and the repackaged *nembutal capsules* were labeled in part "Nembutal 1 Evening upon retiring."

NATURE OF CHARGE: Misbranding, Section 502 (d), the *seconal pulvules* and the *nembutal capsules* were drugs for use by man and contained a chemical derivative of barbituric acid, which derivative had been found, by the Administrator of the Federal Security Agency, after investigation, to be and by regulations designated as habit-forming, and the labels of the repackaged drugs failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith, the statement "Warning - May be habit-forming."

Misbranding, Section 502 (e) (2), the *thyroid tablets* were fabricated from 2 or more ingredients, and the label of the repackaged tablets failed to bear the common or usual name of each active ingredient, including the name and quantity or proportion of thyroid contained therein.

Misbranding, Section 502 (f) (1), the labeling of the *sulfathiazole tablets* and the *thyroid tablets* and the *nembutal capsules* was inadequate, since the repackaged *sulfathiazole tablets* bore no labeling containing directions for use, and since the directions "1 before meals twice daily" and "1 Evening upon retiring" on the boxes of the *thyroid tablets* and the *nembutal capsules*, respectively, were not adequate directions for use.

Misbranding, Section 502 (f) (2), the repackaged *sulfathiazole tablets* and the *thyroid tablets* and the *nembutal capsules* bore no labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health and against unsafe dosage and methods and duration of administration.

Misbranding, Section 502 (j), the repackaged *thyroid tablets* were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling thereof, "1 before meal twice daily."

DISPOSITION: June 4, 1947. A plea of guilty having been entered, the court imposed a fine of \$50 on each of the 4 counts of the information.

2252. Misbranding of Brown's Neuritis Capsules. U. S. v. Randal J. Brown (Thomas A. Brown Pharmacy). Plea of nolo contendere. Defendant fined \$200 and placed on probation for 1 year. (F. D. C. No. 21435. Sample Nos. 5433-H, 5439-H, 5440-H.)

INFORMATION FILED: December 13, 1946, District of New Jersey, against Randal J. Brown, trading as the Thomas A. Brown Pharmacy, Trenton, N. J.

ALLEGED SHIPMENT: On or about January 24 and February 19 and 20, 1946, from the State of New Jersey into the States of Delaware and Pennsylvania.

PRODUCT: Analyses disclosed that the product was a gelatin capsule containing a mixture of about 5 grains of cinchophen, with acetophenetidin, caffeine, emodin bearing drugs, and other materials.

NATURE OF CHARGE: Misbranding, Section 502 (a), the name of the article *Neuritis Capsules* was false and misleading, since it represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of neuritis, whereas the article would not be efficacious for such purposes; Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents, in that the bottle containing the article bore no label containing a statement of the quantity of the contents; and, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from 2 or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, in that the article, by reason of the

fact that it contained cinchophen, was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, i. e., "One every 3 hours, follow with glass of water."

DISPOSITION: April 7, 1947. A plea of nolo contendere having been entered, the court imposed a fine of \$200 on count 3 of the information. With respect to counts 1 and 2 of the information, the court suspended the imposition of sentence and placed the defendant on probation for 1 year, conditioned that he do nothing in conflict with the Federal Food, Drug, and Cosmetic Act, and that he stop the use of cinchophen, unless it appears in a prescription of a duly authorized physician.

2253. Misbranding of devices known as Anatatherm. U. S. v. 5 Devices * * *. (F. D. C. No. 23194. Sample No. 22246-H.)

LIBLE FILED: June 17, 1947, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about May 31, 1946, by the Miller Electro Research Laboratories, from Milwaukee, Wis.

PRODUCT: 5 devices known as *Anatatherm* at St. Louis, Mo., together with 12 circulars entitled "How the Anatatherm SW 150 Short Wave internal heat treatment relieves, corrects, stimulates" and 6 circulars entitled "The New Anatatherm Short Wave Internal Heat Treatment for Health." Examination showed that *Anatatherm* was a device to apply short radio waves to the body.

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used with the frequency or duration prescribed, recommended, and suggested in its labeling, i. e., "Treatment Duration: Apply average power of *Anatatherm* for a period not to exceed one half hour. Three to four treatments per day are generally permissible."

Further misbranding, Section 502 (a), certain statements on the direction cards packed with the article and in the above-mentioned circulars accompanying the article were false and misleading. These statements represented and suggested that the article may be safely and efficaciously used in the treatment of impaired health, sluggish bowels, biliousness, gas pains, intestinal flu, colitis, painful hemorrhoids, prostatitis, colds, painful breathing, catarrhal congestion, asthmatic conditions, localized inflammation, neuralgia myalgia, chronic localized arthritis, arthritis deformans, tired, aching joints, neuritis, sluggish kidneys, grippe, contusions, muscle strains, myositis ossificans, sprains and dislocations, traumatic tenosynovitis, chronic arthritis, myositis and myofascitis (lumbago), fractures, genito-urinary conditions, pelvic infections, respiratory diseases, gastrointestinal diseases, acute and chronic sinusitis, diabetes, paralysis, abscesses, articular rheumatism, asthma, backache, bladder disorders, blood clot, boils, Bright's disease, bronchitis, bursitis, catarrh, carbuncle, colic, congestion, constipation, convulsions, cough, cystitis, deafness, discharge, dropsy, ear disorders, felon, fever, fistula, fracture, furuncles, gall bladder inflammation, gas pressure, headaches, hepatic disorders, hemorrhoids, indigestion, influenza, jaundice, kidney inflammation, laryngitis, lesions, lumbago, mastoiditis, muscular tension, nausea, nephritis, osteitis, ovaritis, peritonitis, pharyngitis, phlebitis, pleurisy, pneumonia, quinsy, rheumatism, salpingitis, sciatica, silicosis, stiff neck, synovitis, teeth abscess, thrombosis, tonsillitis, tooth extractions, ulcers, and whooping cough. The article may not be safely used and was not efficacious in the treatment of such diseases, conditions, and symptoms.

DISPOSITION: December 3, 1947. The Miller Electro Research Laboratories, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2254. Misbranding of sulfathiazole tablets. U. S. v. Jordan James Sullivan (Sullivan's Pharmacy). Tried to the court. Judgment for the Government. Defendant fined \$200 and placed on two years' probation.Appealed to the Circuit Court of Appeals; judgment of District Court reversed. Certiorari to Supreme Court; judgment of District Court affirmed. (F. D. C. No. 16600. Sample Nos. 64091-F, 64236-F.)

INFORMATION FILED: January 2, 1946, Middle District of Georgia, against Jordan James Sullivan, trading as Sullivan's Pharmacy, at Columbus, Ga.

*See also Nos. 2251, 2255.

ALLEGED SHIPMENT: Between the approximate dates of November 25, 1943, to March 15, 1944, from the State of Illinois into the State of Georgia.

LABEL, IN PART: (When shipped) "1000 Tablets (Bisected) SULFATHIAZOLE (2-sulfanilamidothiazole) 0.5 gm. (7.7 grs.) Abbott-List No. 3430 Caution—To be used only by or on the prescription of a physician * * * Abbott Laboratories North Chicago, Ill., U. S. A."

ALLEGED VIOLATION: On or about September 29 and December 13, 1944, while the drug was being held for sale after shipment in interstate commerce, the defendant caused a number of tablets to be removed from the bottles in which they had been shipped in interstate commerce and caused them to be repacked in boxes bearing no other label than the statement "Sulfothiazal" or "Sulfathiazole," which acts caused the article to be misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling on the box failed to bear adequate directions for use; and, Section 502 (f) (2), it failed to bear such adequate warnings against use in those pathological conditions where the use of the article may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: On September 2, 1946, the case was tried to the court and the defendant was convicted. The sentence of the court was that the defendant pay a fine of \$200, and that he be placed on probation for 2 years. On May 12, 1947, the case having been appealed to the Circuit Court of Appeals for the Fifth Circuit, the judgment of the District Court was reversed. The Government petitioned the Supreme Court for a writ of certiorari, which was granted; and on January 19, 1948, the following opinion was delivered by the Supreme Court, reversing the Circuit Court of Appeals and sustaining the judgment of the District Court, with Justices Frankfurter, Reed, and Jackson dissenting:

JUSTICE BLACK: "Respondent, a retail druggist in Columbus, Georgia, was charged in two counts of an information with a violation of § 301 (k) of the Federal Food, Drug, and Cosmetics Act of 1938. That section prohibits 'the doing of any . . . act with respect to, a . . . drug . . . if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded.'¹ Section 502 (f) of the Act declares a drug 'to be misbranded . . . unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use . . . dangerous to health, or against unsafe dosage . . . as are necessary for the protection of users.' The information charged specifically that the respondent had performed certain acts which resulted in sulfathiazole being 'misbranded' while 'held for sale after shipment in interstate commerce.'

"The facts alleged were these: A laboratory had shipped in interstate commerce from Chicago, Illinois, to a consignee at Atlanta, Georgia, a number of bottles, each containing 1,000 sulfathiazole tablets. These bottles had labels affixed to them, which, as required by § 502 (f) (1) and (2) of the Act, set out adequate directions for the use of the tablets and adequate warnings to protect ultimate consumers from dangers incident to this use.² Respondent bought one of these properly labeled bottles of sulfathiazole tablets from the Atlanta

¹ "Sec. 301. The following acts and the causing thereof are hereby prohibited:

* * * * *

"(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded." 52 Stat. 1042, 21 U. S. C. § 331 (k).

² The following inscription appeared on the bottle labels as a compliance with § 502 (f) (1) which requires directions as to use: "Caution.—To be used only by or on the prescription of a physician." This would appear to constitute adequate directions since it is required by regulation issued by the Administrator pursuant to authority of the Act. 21 C. F. R. Cum. Supp. § 2.106 (b) (3). The following appeared on the label of the bottles as a compliance with § 502 (f) (2) which requires warnings of danger: "Warning.—In some individuals Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended.

"Physicians should familiarize themselves with the use of this product before it is administered. A circular giving full directions and contraindications will be furnished upon request."

consignee, transferred it to his Columbus, Georgia, drugstore, and there held the tablets for resale. On two separate occasions twelve tablets were removed from the properly labeled and branded bottle, placed in pill boxes, and sold to customers. These boxes were labeled 'sulfathiazole.' They did not contain the statutorily required adequate directions for use or warnings of danger.

"Respondent's motion to dismiss the information was overruled, a jury was waived, evidence was heard, and respondent was convicted under both counts.

"The Circuit Court of Appeals reversed. 161 F. 2d 629. The court thought that as a result of respondent's action the sulfathiazole became 'misbranded' within the meaning of the Federal Act, and that in its 'broadest possible sense' the Act's language 'may include what happened.' However, it was also of the opinion that the Act ought not to be taken so broadly but held to apply only to the holding for the first sale by the importer after interstate shipment.' Thus the Circuit Court of Appeals interpreted the statutory language of § 301 (k) 'while such article is held for sale after shipment in interstate commerce' as though Congress had said 'while such article is held for sale by a person who had himself received it by way of a shipment in interstate commerce.' We granted certiorari to review this important question concerning the Act's coverage.

"First. The narrow construction given § 301 (k) rested not so much upon its language as upon the Circuit Court's view of the consequences that might result from the broader interpretation urged by the Government. The court pointed out that the retail sales here involved were made in Columbus nine months after this sulfathiazole had been shipped from Chicago to Atlanta. It was impressed by the fact that, if the statutory language 'while such article is held for sale after shipment in interstate commerce' should be given its literal meaning, the criminal provisions relied on would 'apply to all intrastate sales of imported drugs after any number of intermediate sales within the State and after any lapse of time; and not only to such sales of drugs, but also to similar retail sales of food, devices and cosmetics, for all these are equally covered by these provisions of the Act.' The court emphasized that such consequences would result in far-reaching intrusions upon customary control by local authorities of traditionally local activities, and that a purpose to afford local retail purchasers federal protection from harmful foods, drugs and cosmetics should not be ascribed to Congress in the absence of an exceptionally clear mandate, citing *Federal Trade Commission v. Bunte Bros.*, 312 U. S. 349. Another reason of the court for refraining from construing the Act as applicable to articles misbranded while held for retail sale, even though the articles had previously been shipped in interstate commerce, was its opinion that such a construction would raise grave doubts as to the Act's constitutionality. In support of this position the court cited *Labor Board v. Jones & Laughlin Steel Corp.*, 301 U. S. 1, 30, and *Schechter Poultry Corp. v. United States*, 295 U. S. 495.

"A restrictive interpretation should not be given a statute merely because Congress has chosen to depart from custom or because giving effect to the express language employed by Congress might require a court to face a constitutional question. And none of the foregoing cases, nor any other on which they relied, authorizes a court in interpreting a statute to depart from its clear meaning. When it is reasonably plain that Congress meant its Act to prohibit certain conduct, no one of the above references justifies a distortion of the congressional purpose, not even if the clearly correct purpose makes marked deviations from custom or leads inevitably to a holding of constitutional invalidity. Although criminal statutes must be so precise and unambiguous that the ordinary person can know how to avoid unlawful conduct, see *Krauss & Bros., Inc. v. United States*, 327 U. S. 614, 621-622, even in determining whether such statutes meet that test, they should be given their fair meaning in accord with the evident intent of Congress. *United States v. Raynor*, 302 U. S. 540, 552.

"Second. Another consideration that moved the Circuit Court of Appeals to give the statute a narrow construction was its belief that the holding in this case with reference to misbranding of drugs by a retail druggist would necessarily apply also to 'similar retail sales of food, devices and cosmetics, for all of these,' the court said, 'are equally covered by the same provisions of the Act.' And in this Court the effect of such a possible coverage of the Act is graphically magnified. We are told that its application to these local

sales of sulfathiazole would logically require all retail grocers and beauty parlor operators to reproduce the bulk container labels on each individual item when it is taken from the container to sell to a purchaser. It is even prophesied that, if § 301 (k) is given the interpretation urged by the Government, it will later be applied so as to require retail merchants to label sticks of candy and sardines when removed from their containers for sale.

"The scope of the offense which Congress defined is not to be judicially narrowed as applied to drugs by envisioning extreme possible applications of its different misbranding provisions which relate to food, cosmetics, and the like. There will be opportunity enough to consider such contingencies should they ever arise. It may now be noted, however, that the Administrator of the Act is given rather broad discretion—broad enough undoubtedly to enable him to perform his duties fairly without wasting his efforts on what may be no more than technical infractions of law. As an illustration of the Administrator's discretion, § 306 permits him to excuse minor violations with a warning if he believes that the public interest will thereby be adequately served. And the Administrator is given extensive authority under §§ 405, 503 and 603 to issue regulations exempting from the labeling requirements many articles that otherwise would fall within this portion of the Act. The provisions of § 405 with regard to food apparently are broad enough to permit the relaxation of some of the labeling requirements which might otherwise impose a burden on retailers out of proportion to their value to the consumer.

"Third. When we seek the meaning of § 301 (k) from its language we find that the offense it creates and which is here charged requires the doing of some act with respect to a drug (1) which results in its being misbranded, (2) while the article is held for sale 'after shipment in interstate commerce.' Respondent has not seriously contended that the 'misbranded' portion of § 301 (k) is ambiguous. Section 502 (f), as has been seen, provides that a drug is misbranded unless the labeling contains adequate directions and adequate warnings. The labeling here did not contain the information which § 502 (f) requires. There is a suggestion here that, although alteration, mutilation, destruction, or obliteration of the bottle label would have been a 'misbranding,' transferring the pills to non-branded boxes would not have been, so long as the labeling on the empty bottle was not disturbed. Such an argument cannot be sustained. For the chief purpose of forbidding the destruction of the label is to keep it intact for the information and protection of the consumer. That purpose would be frustrated when the pills the consumer buys are not labeled as required, whether the label has been torn from the original container or the pills have been transferred from it to a non-labeled one. We find no ambiguity in the misbranding language of the Act.

"Furthermore, it would require great ingenuity to discover ambiguity in the additional requirement of § 301 (k) that the misbranding occur 'while such article is held for sale after shipment in interstate commerce.' The words accurately describe respondent's conduct here. He held the drugs for sale after they had been shipped in interstate commerce from Chicago to Atlanta. It is true that respondent bought them nine months after the interstate shipment had been completed by their delivery to another consignee. But the language used by Congress broadly and unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intra-state sales had intervened, or who had received the articles at the end of the interstate shipment. Accordingly we find that the conduct of the respondent falls within the literal language of § 301 (k).

"Fourth. Given the meaning that we have found the literal language of § 301 (k) to have, it is thoroughly consistent with the general aims and purposes of the Act. For the Act as a whole was designed primarily to protect consumers from dangerous products. This Court so recognized in *United States v. Dotterweich*, 320 U. S. 277, 282, after reviewing the House and Senate Committee Reports on the bill that became law. Its purpose was to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer. Section 301 (a) forbids the 'introduction or delivery for introduction into interstate commerce' of misbranded or adulterated drugs; § 301 (b) forbids the misbranding or adulteration of drugs while 'in interstate commerce'; and § 301 (c) prohibits the

'receipt in interstate commerce' of any misbranded or adulterated drug, and 'the delivery or proffered delivery thereof for pay or otherwise.' But these three paragraphs alone would not supply protection all the way to the consumer. The words of paragraph (k) 'while such article is held for sale after shipment in interstate commerce' apparently were designed to fill this gap and to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer. Doubtless it was this purpose to insure federal protection until the very moment the articles passed into the hands of the consumer by way of an intrastate transaction that moved the House Committee on Interstate and Foreign Commerce to report on this section of the Act as follows: 'In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment.'³ We hold that § 301 (k) prohibits the misbranding charged in the information.

Fifth. It is contended that the Act as we have construed it is beyond any authority granted Congress by the Constitution and that it invades the power of the States. A similar challenge was made against the Pure Food and Drug Act of 1906, 34 Stat. 768, and rejected, in *McDermott v. Wisconsin*, 228 U. S. 115. That Act did not contain § 301 (k), but it did prohibit misbranding and authorized seizure of misbranded articles after they were shipped from one State to another, so long as they remained 'unsold.' The authority of Congress to make this requirement was upheld as a proper exercise of its powers under the commerce clause. There are two variants between the circumstances of that case and this one. In the *McDermott* case the labels involved were on the original containers; here the labels are required to be put on other than the original containers—the boxes to which the tablets were transferred. Also, in the *McDermott* case the possessor of the labeled cans held for sale had himself received them by way of an interstate sale and shipment; here, while the petitioner had received the sulfathiazole by way of an intrastate sale and shipment, he bought it from a wholesaler who had received it as the direct consignee of an interstate shipment. These variants are not sufficient we think to detract from the applicability of the *McDermott* holding to the present decision. In both cases alike the question relates to the constitutional power of Congress under the commerce clause to regulate the branding of articles that have completed an interstate shipment and are being held for future sales in purely local or intrastate commerce. The reasons given for the *McDermott* holding therefore are equally applicable and persuasive here. And many cases decided since the *McDermott* decision lend support to the validity of § 301 (k). See, e. g., *United States v. Walsh*, 331 U. S. 432; *Wickard v. Filburn*, 317 U. S. 111; *United States v. Wrightwood Dairy Co.*, 315 U. S. 110; *United States v. Darby*, 312 U. S. 100; see *United States v. Olsen*, 161 F. 2d 669. *Reversed.*"

JUSTICE RUTLEDGE, concurring: "This case has been presented as if the Federal Food, Drug, and Cosmetics Act of 1938 had posed an inescapable dilemma. It is said that we must either (1) ignore Congress' obvious intention to protect ultimate consumers of drugs through labeling requirements literally and plainly made applicable to the sales in this case or (2) make criminal every corner grocer who takes a stick of candy from a properly labeled container and sells it to a child without wrapping it in a similar label.

"The trouble-making factor is not found in the statute's provisions relating specifically to drugs. Those provisions taken by themselves are clear and unequivocal in the expressed purpose to protect the ultimate consumer by the labeling requirements. So is the legislative history. Standing alone, therefore, the drug provisions would cover this case without room for serious question.

"However, those provisions do not stand entirely separate and independent in the Act's structure. In some respects, particularly in § 301 (k), they are interlaced with provisions affecting food and cosmetics. And from this fact is drawn the conclusion that this decision necessarily will control future decisions concerning those very different commodities.

³ H. Rep. 2139, 75th Cong., 3d Sess., 3.

"If the statute as written required this, furnishing no substantial basis for differentiating such cases, the decision here would be more difficult than I conceive it to be. But I do not think the statute has laid the trap with which we are said to be faced. Only an oversimplified view of its terms and effects could produce that result.

"The Act is long and complicated. Its numerous provisions treat the very different subjects of drugs, food and cosmetics alike in some respects, differently in others. The differences are as important as the similarities, and cannot be ignored. More is necessary for construction of the statute than looking merely to the terms of §§ 301 (k) and 502 (f).

"It is true that § 301 (k) deals indiscriminately with food, drugs, devices and cosmetics, on the surface of its terms alone. Hence it is said that the transfer of sulfathiazole, a highly dangerous drug, from a bulk container to a small box for retail sale, could not be 'any other act' unless a similar transfer of candies, usually harmless, also would be 'any other act.' From this hypothesis it is then concluded that the phrase must be interpreted with reference to the particularities which precede it, namely, 'alteration, mutilation, destruction, obliteration or removal' of any part of the label, and must be limited by those particularities.

"That construction almost, if not quite, removes 'any other act' from the section. And by doing so it goes far to emasculate the section's effective enforcement, especially in relation to drugs. Any dealer holding drugs for sale after shipment in interstate commerce could avoid the statute's effect simply by leaving the label intact, removing the contents from the bulk container, and selling them, however deadly, in broken parcels without label or warning.

"I do not think Congress meant the phrase to be so disastrously limited. For the 'doing of any other act with respect to, a food, drug, device, or cosmetic' is prohibited by § 301 (k) only 'if such act . . . results in such article being misbranded.' And the statute provides, not a single common definition of misbranding for foods, drugs and cosmetics, but separate and differing sections on misbranded foods, misbranded drugs and devices, and misbranded cosmetics. §§ 403, 502, 602.

"The term 'misbranded' as used in § 301 (k) therefore is not one of uniform connotation. On the contrary, its meaning is variable in relation to the different commodities and the sections defining their misbranding. So also necessarily is the meaning of 'any other act,' which produces those misbranding consequences. Each of the three sections therefore must be taken into account in determining the meaning and intended scope of application for § 301 (k) in relation to the specific type of commodity involved in the particular sale, if Congress' will is not to be overridden by broadside generalization glossed upon the statute. As might have been expected, Congress did not lump food, drugs and cosmetics in one indiscriminate hopper for the purpose of applying § 301 (k), either in respect to misbranding or as to 'any other act' which produces that consequence. Brief reference to the several misbranding sections incorporated by reference in § 301 (k) substantiates this conclusion.

"The three sections contain some common provision.⁴ But the fact that each section is also different from the other two in important respects indicates that each broad subdivision of the Act presents different problems of interpretation. Neither the misbranded foods section nor the misbranded cosmetics section contains any provision directly comparable to § 502 (f), which the respondent here has violated. That section, however, is to be contrasted with § 403 (k), one of the subsections dealing with misbranded foods. Comparison of the two provisions indicates that the doing of a particular act with respect to a drug may result in misbranding, whereas the same method of selling food would be proper.

"Section 502 (f) provides that a drug shall be deemed to be misbranded:

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement.

⁴ E. g., §§ 403 (a), 502 (a) and 602 (a) are in identical language.

"This provision, dealing with directions for use and warnings against improper use, in terms is designed 'for the protection of users.' To be effective, this protection requires regulation of the label which the container bears when the drug reaches the ultimate consumer.⁵ The legislative history leaves no doubt that the draftsmen and sponsors realized the importance of having dangerous drugs properly labeled at the time of use, not just at the time of sale.⁶ The intent to protect the public health is further emphasized by the limited scope of the proviso, which directs the Administrator to make exemptions only when compliance with clause (1) 'is not necessary for the protection of the public health.'

"Section 403 (k), which contains the principal basis for 'making every retail grocer a criminal,' is very different. By its terms food is deemed to be misbranded:

If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Administrator. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

"The section, in contrast to § 502 (f)'s comprehensive coverage of drugs, applies not to all foods shipped interstate, but only to the restricted classes containing artificial flavoring, or coloring, or chemical preservatives. The labeling requirement is much simpler. And the proviso confers a much broader power of exemption upon the Administrator than does the proviso of § 502 (f). Under the latter he is given no power to exempt on the ground that compliance is impracticable. He cannot weigh business convenience against protection of the public health. Only where he finds that labeling is not necessary to that protection is he authorized to create an exemption for drugs and devices. Health security is not only the first, it is the exclusive, criterion.

"Under § 403 (k), however, in dealing with foods the Administrator can dispense with labels much more broadly. In terms the criterion for his action becomes 'the extent that compliance . . . is impracticable' rather than, as under § 502 (f), 'where any requirement of clause (1) [adequate directions for use] . . . is not necessary for the protection of the public health.' Practical considerations affecting the burden of compliance by manufacturers and retailers, irrelevant under § 502 (f), become controlling under § 403 (k). Thus under the statute's intent a much more rigid and invariable compliance with the labeling requirements for drugs is contemplated than for those with foods, apart from its greatly narrower coverage of the latter. And the difficulty of compliance with those requirements for such articles as candies explains the difference in the two provisos.⁷

"These differences, and particularly the differences in the provisos, have a direct and an intended relation to the problem of enforcement. The labeling requirements for foods are given much narrower and more selective scope for application than those for drugs, a difference magnified by the conversely differing room allowed for exemptions. What is perhaps equally important, the provisos are relevant to enforcement beyond specific action taken by the Administrator to create exemptions.

"His duty under both sections is cast in mandatory terms. Whether or not he can be forced by mandamus to act in certain situations, his failure to act in some would seem to be clearly in violation of his duty. Obviously there must be many more instances where compliance with the labeling requirements for foods will be 'impracticable' than where compliance with the very different requirements for drugs will not be 'necessary for the protection of the public.'

⁵ See S. Rep. No. 361, 74th Cong., 1st Sess. 19.

⁶ See H. R. Rep. No. 2139, 75th Cong., 3d Sess. 8.

⁷ "The proviso of this paragraph likewise requires the establishment of regulations exempting packages of assorted foods from the naming of ingredients or from their appearance in the order of predominance by weight where, under good manufacturing practice, label declaration of such information is impracticable. This provision will be particularly applicable, for example, to assorted confections, which under normal manufacturing practices may vary from package to package not only with respect to identity of ingredients but also in regard to the relative proportions of such ingredients as are common to all packages." S. Rep. No. 493, 73d Cong., 2d Sess. 12. The proviso discussed is in § 403 (i), not in § 403 (k); but the discussion brings out the sort of considerations which require exemption when compliance is impracticable.

health.' That difference is obviously important for enforcement, particularly by criminal prosecution. I think it is one which courts are entitled to take into account when called upon to punish violations. The authors of the legislation recognized expressly that 'technical, innocent violations . . . will frequently arise.' S. Rep. No. 152, 75th Cong., 1st Sess. 4. In other words, there will be conduct which may be prohibited by the Act's literal wording, but which nevertheless should be immune to prosecution.

"When that situation arises, as it often may with reference to foods, by virtue of the Administrator's failure to discharge his duty to create exemptions before the dealer's questioned action takes place, that failure in my judgment is a matter for the court's consideration in determining whether prosecution should proceed. Whenever it is made to appear that the violation is a 'technical, innocent' one, an act for which the Administrator should have made exemption as required by § 403 (k), the prosecution should be stopped. This Court has not hesitated to direct retroactive administrative determination of private rights when that unusual course seemed to it the appropriate solution for their determination. *Addison v. Holly Hill Fruit Products*, 322 U. S. 607. If that is permissible in civil litigation, there is much greater reason for the analogous step of taking into account in a criminal prosecution an administrative officer's failure to act when the commanded action, if taken, would have made prosecution impossible.

"It is clear therefore that the corner grocer occupies no such position of jeopardy under this legislation as the druggist, and that the meaning of § 301 (k) is not identical for the two, either as to what amounts to misbranding or as to what is 'the doing of any . . . act' creating that result. The supposed dilemma is false. Congress had power to impose the drug restrictions, they are clearly applicable to this case, the decision does not rule the corner grocer selling candy, and the judgment should be reversed. I therefore join in the Court's judgment and opinion to that effect."

JUSTICE FRANKFURTER, dissenting: "If it takes nine pages to determine the scope of a statute, its meaning can hardly be so clear that he who runs may read, or that even he who reads may read. Generalities regarding the effect to be given to the 'clear meaning' of a statute do not make the meaning of a particular statute 'clear.' The Court's opinion barely faces what, on the balance of considerations, seems to me to be the controlling difficulty in its rendering of § 301 (k) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 1042; 21 U. S. C. § 331 (k). That section no doubt relates to articles 'held for sale after shipment in interstate commerce and results in such article being misbranded.' But an article is 'misbranded' only if there is 'alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic.' Here there was no 'alteration, mutilation, destruction, obliteration, or removal' of any part of the label. The decisive question is whether taking a unit from a container and putting it in a bag, whether it be food, drug or cosmetic, is doing 'any other act' in the context in which that phrase is used in the setting of the Federal Food, Drug, and Cosmetic Act and particularly of § 301 (k).⁸

"As bearing upon the appropriate answer to this question, it cannot be that a transfer from a jar, the bulk container, to a small paper bag, without transferring the label of the jar to the paper bag, is 'any other act' when applied to a drug, but not 'any other act' when applied to candies or cosmetics. Before we reach the possible discretion that may be exercised in prosecuting a certain conduct, it must be determined whether there is anything to prosecute. Therefore, it cannot be put off to some other day to determine whether 'any other act' in § 301 (k) applies to the ordinary retail sale of candies or cosmetics in every drug store or grocery throughout the land, and so places every corner grocery and drug store under the hazard that the Administrator may report such conduct for prosecution. That question is now here. It is part of this very case, for the simple reason that the prohibited conduct of § 301 (k) applies with equal force, through the same phrase, to food, drugs

⁸ "The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

and cosmetics insofar as they are required to be labeled. See §§ 403, 502, and 602 of the Act.

"It is this inescapable conjunction of food, drugs and cosmetics in the prohibition of § 301 (k) that calls for a consideration of the phrase 'or the doing of any other act,' in the context of the rest of the sentence and with due regard for the important fact that the States are also deeply concerned with the protection of the health and welfare of their citizens on transactions peculiarly within local enforcing powers. So considered, 'the doing of any other act' should be read with the meaning which radiates to that loose phrase from the particularities that precede it, namely 'alteration, mutilation, destruction, obliteration, or removal' of any part of the label. To disregard all these considerations and then find 'a clear meaning' is to reach a sum by omitting figures to be added. There is nothing in the legislative history of the Act, including the excerpt from the Committee Report on which reliance is placed, to give the slightest basis for inferring that Congress contemplated what the Court now finds in the statute. The statute in its entirety was of course intended to protect the ultimate consumer. This is no more true in regard to the requirements pertaining to drugs than of those pertaining to food. As to the reach of the statute—the means by which its ultimate purpose is to be achieved—the legislative history sheds precisely the same light on the provisions pertaining to food as on the provisions pertaining to drugs. If differentiations are to be made in the enforcement of the Act and in the meaning which the ordinary person is to derive from the Act, such differentiations are interpolations of construction. They are not expressions by Congress.

"In the light of this approach to the problem of construction presented by this Act, I would affirm the judgment below.

"MR. JUSTICE REED and MR. JUSTICE JACKSON join in this dissent."

- 2255. Misbranding of Manning's Whoa Liniment, Bi-Lax Capsules, Manning's Fumigating Powder, Manix, Formula for Catarrh of the Bladder, Formula for Relief of High Blood Pressure, Formula for Relief of Coughs, and Formula for Asthma. U. S. v. Donald R. Manning (Manning Herb House). Plea of guilty. Sentence of 30 days in jail on count 1 and 3 years' probation on counts 2 to 8, incl.; probation revoked, and defendant fined \$750. (F. D. C. No. 14280. Sample Nos. 41257-F, 46492-F, 46493-F, 52069-F, 52071-F, 52074-F, 52076-F, 52077-F.)**

INFORMATION FILED: April 3, 1945, Northern District of Alabama, against Donald R. Manning, trading as the Manning Herb House, Bessemer, Ala.

ALLEGED SHIPMENT: On or about August 31 and October 19, 1943, and February 21, 1944, from the State of Alabama into the States of Illinois, Massachusetts, and Mississippi.

PRODUCT: Analyses disclosed that *Manning's Whoa Liniment* consisted essentially of a petroleum distillate containing small portions of mustard oil, camphor, clove oil, and capsicum; that the *Formula for Catarrh of the Bladder* consisted of ground buchu leaves and leaves of the *Prunus* species, probably peach; that the *Formula for Relief of High Blood Pressure* consisted of coarsely ground mistletoe herb; that the *Bi-Lax Capsules* consisted essentially of blue mass (mercury derivative) 0.42 grain per capsule, aloe, soap, and capsicum; that *Manning's Fumigating Powder* consisted essentially of plant material, including cubeb and potassium nitrate; that the *Formula for Relief of Coughs* consisted of a mixture of the powdered pod and seed tissues of St. John's Bread, together with the ground leafy twigs of arbor vitae; that the *Manix* consisted of two immiscible layers, the upper layer consisting essentially of fish oil and the lower layer consisting essentially of extracts of plant drugs, glycerin, sugar, and water; and that the *Formula for Asthma* consisted essentially of plant material, either in solution or suspension, and water.

NATURE OF CHARGE: *Manning's Whoa Liniment*. Misbranding, Section 502 (a), certain statements in an accompanying circular entitled "True Testimonial Booklet" were false and misleading. These statements represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of the following conditions: Inability to stand for more than 15 minutes, condition requiring the patient to lie flat on the back and to have his meals in bed, rheumatism, stiffness in both legs, difficulty in walking, aching from the ovaries to the toes, inability to stoop, pain in the side, headache, stiffness and soreness in the joints, aching joints, toothache, and bad corns. The statements represented and suggested also that the article would be

efficacious to enable a person with aching neck, head, and legs, to walk and work in comfort. The article would not be efficacious for such purposes.

Bi-Lax Capsules. Misbranding, Section 502 (a), the label statement "One capsule daily as a palliative relief for disorder of stomach and bowels" was false and misleading, since the article would not be efficacious as a relief for disorder of the stomach and bowels. Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium, and it was fabricated from two or more ingredients, one of which was blue mass, a preparation of mercury; and the label of the article failed to bear a statement of the quantity or proportion of mercury contained in the article and a statement that blue mass is a preparation of mercury. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, since the article was a laxative and its labeling failed to warn against its use in the presence of abdominal pain, severe vomiting, or other symptoms of appendicitis; and its labeling failed also to bear adequate warning against unsafe dosage or methods or duration of administration, since it contained blue mass, a preparation of mercury, and prolonged or frequent use of amounts in excess of the prescribed directions, may cause serious mercury poisoning; and its label failed to warn of the danger of mercury poisoning resulting from such uses, and, further, the labeling of the article failed to warn that frequent and continued use of a laxative may result in dependence on a laxative to move the bowels.

Manning's Fumigating Powder. Misbranding, Section 502 (a), certain label statements were false and misleading, since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of hay fever, catarrh, and the similar conditions indicated and suggested by the abbreviation "etc." The article would not be efficacious for such purposes. Further misbranding, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents.

Formula for Catarrh of the Bladder, Formula for Relief of High Blood Pressure, Formula for Relief of Coughs, and Formula for Asthma. Misbranding, Section 502 (a), the statements in the labeling "Catarrh of the Bladder," "For Relief of High Blood Pressure," "For Relief of Coughs," and "Asthma," were false and misleading, since the products would not be effective for the purposes represented and suggested.

DISPOSITION: October 18, 1945. A plea of guilty having been entered, the court imposed a sentence of 30 days in jail on count 1 relating to *Manning's Whoa Liniment* and placed the defendant on probation for a period of 3 years on the remaining 7 counts.

Subsequent to the sentence, a complaint was filed against the defendant by the probation officer, charging violation of the probation. On November 15, 1946, after a hearing, the court ordered the probation revoked and sentenced the defendant to pay a fine of \$750. Thereupon, the defendant filed an appeal to the Circuit Court of Appeals for the Fifth Circuit, which, on May 28, 1947, handed down the following decision, affirming the action of the District Court in revoking the probation:

McCord, Circuit Judge: "On October 18, 1945, on plea of guilty, Donald R. Manning was convicted on eight counts of an information charging him with unlawfully introducing in interstate commerce a number of packages containing drugs which had been misbranded, all in violation of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 352 (a). Manning was sentenced to thirty days imprisonment under count one, and on the other counts was placed on probation for a period of three years.

"On November 13, 1946, the probation officer filed a complaint charging that Manning had violated the conditions of his probation. The matter came up for hearing on November 15, 1946, and Manning moved for a more definite and formal complaint setting out the charges against him. The motion was denied, but there was filed a statement which recited: 'Violations of Conditions of Probation: 1 Practicing medicine without a license during period from May 1, 1946, to August 31, 1946. 2. On or about May 9, 1946, used the mails to defraud Charles Ebel of Box 117, Cherokee, Ala. 3. On or about August 26, 1946, used the mails to defraud M. T. Hanson, Repton, Ala. 4. On or about August 26, 1946, used the mails to defraud Olive Harold of Box 369, Bay Minette, Ala.' The hearing was continued until November 22, 1946, and was then conducted before

the district judge that had originally placed Manning on probation. Testimony for and against Manning was received, and at the conclusion of the hearing the district judge revoked Manning's probation,⁹ fined him \$750.00, and committed him to the custody of the Attorney General for a period of one year. From the order revoking the probation, Manning has appealed.

"Appellant contends that he was entitled to have in advance a list of adverse witnesses and a more particular specification of the charges against him than was furnished; that there were no conditions of probation pronounced at the time he was placed on probation; and that the evidence at the hearing was not sufficient to justify revocation of probation on either of the theories: (1) that he was using the mails to defraud, (2) that he was practicing medicine without a license, or (3) that he was not leading an honest life as required by the alleged conditions of probation.

"As to appellant's allegations that the complaint against him was not specific enough, it is sufficient to say that a proceeding for revocation of probation is not one of formal procedure 'either with respect to notice or specification of charges or a trial upon charges. The question is simply whether there has been an abuse of discretion and is to be determined in accordance with familiar principles governing the exercise of judicial discretion.' *Burns v. United States*, 287 U. S. 216; *Escoe v. Zerbst*, 295 U. S. 490; *Dillingham v. United States*, 76 F. 2d 35.

"A probationer may not have his probation revoked unless it is made to appear that he has failed to comply with the terms and conditions of his probation. *Mankowski v. United States*, 148 F. 2d 143, 144. Appellant accordingly asserts that no terms or conditions of probation were included in the judgment placing him on probation. This contention is without basis or merit. Since September 21, 1939, there has been in the District Court of the Northern District of Alabama a standing order imposing general conditions of probation.¹⁰ Not only did this order apply to Manning's case, but the conditions in the order were specifically called to his attention in a written statement, of which he received a copy, and for which he gave his receipt in writing.¹¹

"There is no merit in appellant's contention that the evidence was not sufficient to justify revocation of his probation. Action of a trial judge in revoking probation is an exercise of broad discretionary power, and on appeal the question is simply whether there has been an abuse of discretion. *Burns v. United States*, 287 U. S. 216; *Pritchett v. United States*, 67 F. 2d 244. There is abundant evidence in this record from which the trial judge could, and did, conclude that Manning, in the conduct of his herb business, was holding himself out to ignorant people as a doctor; that he was purporting to diagnose ail-

⁹ In revoking the probation, the trial judge stated: "As I see the evidence in this case, I think this man is engaged in a business which constitutes a fraud on the general public. I think he is out there practicing medicine, and I think it should be stopped. And I think he is selling these alleged herb medicines to ignorant people * * * and he is liable to cause them to die from want of proper medical care. * * * It is really based on three things. In the first place, I think he is practicing medicine without a license, and I think he is making a diagnosis of ailments, and, as I said, preparing medicine and representing it will cure. In addition to that, he has signs advertising to Negroes and very ignorant people. I think he is holding himself out to them as a doctor, * * * he is using a stethoscope, and I think under all the facts in this case he is practicing medicine."

As I say, I think it is a fraud on the public which should not be tolerated. They were after him, according to the records that have been furnished me from the Probation Department, about practicing in Georgia without a license. Under his own statement, he was practicing in Georgia without a license, and he has come over here and is making a lot of money out of it. I am revoking his probation, first, on the theory that he is practicing medicine without a license. Second, on the theory he is using the mails to defraud. And, third, on the theory he is not leading an honest life as required by the conditions of probation. In other words, I think he is in a dishonest business and I think it is a fraud on the general public. * * *"

¹⁰ This standing order on probation conditions was not included by appellant in his record on appeal, but this court directed that it be sent up. This order provides, among other things, that a probationer must: "6. Conduct himself or herself honorably, work diligently at a lawful occupation and support his or her dependents, if any, to the best of his or her ability. 9. Not violate any law; local, state or national."

¹¹ The written notice of conditions which Manning received advised him of the general conditions of probation: "The general conditions of probation are as follows: (a) Refrain from the violation of any state and federal penal laws. (b) Live a clean, honest, and temperate life. * * *". Manning admitted that he had received the copy of the conditions of probation. The Court: "I want to ask you if you signed those conditions at the time I placed you on probation in this case?" Manning: "Yes, sir, I did."

ments and was prescribing medicines for their cure; that the medicines which he prescribed and sold by mail were not beneficial, but were, in many instances, absolutely worthless and harmful to the patient; and that Manning was not leading an honest life, but was perpetrating a fraud on the public.

"It may be, as appellant contends, that the evidence on the probation revocation hearing would not be sufficient to support a conviction under federal laws for using the mails to defraud or under Alabama law for practicing medicine without a license. But proof sufficient to support a criminal conviction is not required to support a judge's discretionary order revoking probation. A judge in such proceeding need not have evidence that would establish beyond a reasonable doubt guilt of criminal offenses. All that is required is that the evidence and facts be such as to reasonably satisfy the judge that the conduct of the probationer has not been as good as required by the conditions of probation. *Campbell v. Aderhold*, 36 F. 2d 366; *United States v. Hanson*, 49 F. Supp. 355.

"Manning was given a full, fair, and comprehensive hearing before the trial judge. The record, instead of showing abuse of discretion on the part of the trial judge, discloses a sound exercise of judicial discretion and fully supports the order revoking appellant's probation.

"The judgment is affirmed."

2256. Misbranding of phenobarbital tablets, thyroid tablets, sulfathiazole tablets, sulfanilamide tablets, and sulfanilamide and sodium bicarbonate tablets. U. S. v. Mills Sales Company of New York, Inc., and David Jacoby. Pleas of guilty. Fine of \$1,125 against each defendant. (F. D. C. No. 17862. Sample Nos. 96241-F, 2761-H, 5893-H, 18248-H, 22662-H, 24366-H, 28276-H, 28935-H.)

INFORMATION FILED: May 8, 1947, Southern district of New York, against the Mills Sales Company of New York, Inc., New York, N. Y., and David Jacoby, president of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of May 9, 1944, and April 6, 1945, from the State of New York into the States of Virginia, New Jersey, Iowa, Arkansas, Alabama, Oregon, Idaho, and Indiana.

LABEL, IN PART: (Bottles) "Phenobarbital Tablets * * * Allen Laboratories Distributors, New York, N. Y. * * * To be used only by or on the prescription of a physician," or "Certified Brand Thyroid Tablets" [or "Sulfathiazole Tablets," "Phenobarbital Tablets," "Sulfanilamide Tablets," or "Sulfanilamide and Sodium Bicarbonate Tablets"] * * * To be used only by or on the prescription of a physician * * * Certified Drug & Chemical Co., Distributors New York, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use, in that the bottles containing the articles bore no labeling containing directions for use.

DISPOSITION: June 25, 1947. Pleas of guilty having been entered, the court imposed a fine of \$1,125 against each defendant.

2257. Misbranding of Tescum Powders. U. S. v. Edna Bertha Bramley (Tescum Co.). Plea of guilty. Fine, \$175 and costs. (F. D. C. No. 21450. Sample Nos. 18119-H, 24889-H.)

INFORMATION FILED: May 27, 1947, Northern District of Ohio, against Edna Bertha Bramley, trading as the Tescum Co., at Cleveland, Ohio.

ALLEGED SHIPMENT: From on or about September 10, 1945, to on or about January 8, 1946, from the State of Ohio into the States of Illinois and Texas.

PRODUCT: Analysis disclosed that the product was a white, unflavored powder consisting essentially of sugars, ammonium chloride, and tartar emetic, with a trace of gold and sodium chloride.

LABEL, IN PART: (All packages) "Tescum Powders Tescum produces temporary nausea or vomiting in most cases and should not be used indiscriminately or continuously. Dosage: No more than one powder in liquid every other day * * * Caution: Too frequent use or over dosage will cause intense nausea and may be dangerous"; (on some packages) "Chronic Alcoholism is medically recognized as a disease, in this case consult a physician."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements on the labels of some of the packages were false and misleading. These statements repre-

sented and suggested that the article would be efficacious in the cure, mitigation, and treatment of alcoholism, whereas the article would not be efficacious for such purpose.

Further misbranding, Section 502 (f) (1), the labeling of the remainder of the packages failed to bear adequate directions for use, since they failed to reveal the conditions for which the article was to be used.

DISPOSITION: December 19, 1947. A plea of guilty having been entered, the court imposed a fine of \$175, plus costs.

2258. Misbranding of Forfem Perles. U. S. v. 45 Boxes * * *. (F. D. C. No. 23963. Sample No. 14292-K.)

LIBEL FILED: November 18, 1947, Northern District of Illinois.

ALLEGED SHIPMENT: On or about June 26, 1947, by the Supreme Pharmaceutical Co., from New York, N. Y.

PRODUCT: 45 boxes each containing 24 *Forfem Perles* at Chicago, Ill.

LABEL, IN PART: "Forfem Perles A carefully prepared combination of Pennyroyal, Tansy, Apioi, Powdered Extract of Ergot, Aloin, Rue and Vegetable Oil in a soft Gelatin Perle."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use and did not conform to the conditions authorizing exemption from that requirement, since its label did not bear a statement of the quantity or proportion of each active ingredient in the article.

DISPOSITION: February 25, 1948. Default decree of condemnation and destruction.

2259. Misbranding of 1 Shot A-Ran Treatment. U. S. v. 35 Outfits * * *. (F. D. C. No. 23198. Sample No. 86867-H.)

LIBEL FILED: June 20, 1947, District of Minnesota.

ALLEGED SHIPMENT: On or about February 19 and March 17, 1947, from Green Bay, Wis., by Random Veterinary Products, Inc.

PRODUCT: 35 outfits, each containing 9 envelopes, of *1 Shot A-Ran Treatment*, 1 empty bottle, 1 rubber hose, 1 needle, and 36 envelopes (refills) of *1 Shot A-Ran Treatment*, at Minneapolis, Minn. Analysis showed that the product in the envelope consisted essentially of dextrose and 70 milligrams of acriflavine.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements, "1 Shot A-Ran Treatment For Mastitis Garget * * * Don't Let Garget Steal Your Milk Checks," in the labeling of the article were false and misleading, since they represented and suggested that the article was an adequate treatment for mastitis or garget caused by various infections, whereas the article was not such adequate treatment; Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents, since the package labels failed to bear any statement of the quantity of the contents; Section 502 (e) (1), the article was fabricated from 2 or more ingredients and its label failed to bear the common or usual name of each active ingredient, since the name declared on the label "Diamino-Methylacridine Chloride Diaminoacridine" is not the common or usual name of acriflavine; and, Section 502 (f) (1), the labeling failed to bear adequate directions for use, since the following directions in the labeling were not adequate for the treatment of mastitis or garget: "DIRECTIONS FOR USE: Milking Cows—Dissolve contents of this envelope in pint bottle of sterile or freshly boiled water. Strip out quarter. Hold injection bottle about 3 feet above quarter so that A-Ran solution flows into quarter by gravity without force. Massage quarter gently so entire pint flows into quarter. Leave A-Ran solution in quarter 45 minutes then strip it all out. Treat adjoining quarter with A-Ran to be sure infection has not spread. Treatment may be repeated in one week if needed. Dry Cows—Prepare and inject A-Ran as described above. Leave in quarter for 45 minutes, then strip out. Strip out quarter for next two days to be sure all of solution has been removed. CAUTION—Do not leave A-Ran solution in quarter longer than one hour."

DISPOSITION: October 18, 1947. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2260. Adulteration and misbranding of sodium salicylate ampuls. U. S. v. The Intra Products Co., Claude B. Murdock, and Scott A. Powell. Pleas of guilty. Fines of \$800 against the company, \$400 against Claude B. Murdock, and \$1,000 against Scott A. Powell. (F. D. C. No. 23243. Sample No. 48560-H.)

INFORMATION FILED: September 29, 1947, District of Colorado, against the Intra Products Co., a corporation, Denver, Colo., Claude B. Murdock, president of the corporation, and Scott A. Powell, chemist for the corporation.

ALLEGED SHIPMENT: On or about December 13, 1946, from the State of Colorado into the State of Texas.

LABEL, IN PART: (Box) "10 cc. Intravenous Solution Each 10 cc. Contains: Sodium Salicylate 15.4 gr."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Salicylate," a drug the name of which is recognized in the National Formulary, an official compendium, but its strength, quality, and purity fell below the standard set forth in that compendium since the article yielded not more than 52 percent of the labeled amount of anhydrous sodium salicylate and since it contained undissolved material. The National Formulary provides that *ampuls of sodium salicylate* shall yield not less than 95 percent of the labeled amount of sodium salicylate and must be substantially free of undissolved material. The difference in the strength, quality, and purity of the article from the official standard was not stated on its label. Further adulteration, Section 501 (c) (2), ampuls containing a mixture of sodium salicylate and sodium iodide had been substituted for *ampuls of sodium salicylate*.

Misbranding, Section 502 (a), the label statement "Each 10 cc. Contains: Sodium Salicylate 15.4 gr." was false and misleading, since each 10 cubic centimeters of the article contained less than 15.4 grains of sodium salicylate. (The ampuls contained 8.01 grams of sodium salicylate and 8.28 grams of sodium iodide per 10 cc.)

DISPOSITION: October 21, 1947. Pleas of guilty having been entered, the court imposed fines of \$800 against the corporation, \$400 against Claude Murdock, and \$1,000 against Scott Powell.

2261. Adulteration and misbranding of water for injection. U. S. v. Morton G. Falk (Estro Chemical Co.). Plea of guilty. Fine, \$500. (F. D. C. No. 14310. Sample Nos. 63531-F, 79917-F.)

INFORMATION FILED: August 17, 1945, Southern District of New York, against Morton G. Falk, a member of a partnership trading as the Estro Chemical Co., New York, N. Y.

ALLEGED SHIPMENT: On or about April 28 and June 1, 1944, from the State of New York into the States of Georgia and Maryland.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not free from pyrogens, as required by the standard, but contained pyrogens; it was not a clear liquid, as required by the standard, but contained undissolved material; and the difference in quality and purity of the article from the standard was not plainly stated, or stated at all, on its label.

Misbranding, Section 502 (a), the label statement "Water for Injection U. S. P. XII" was false and misleading, since the article did not consist of water for injection complying with the requirements of the United States Pharmacopoeia; and the statement "Pyrogen Free" borne on the label of the shipment of June 1, 1944, into Maryland, was false and misleading, since the article was not free from pyrogens.

DISPOSITION: April 3, 1947. A plea of guilty having been entered, the court imposed a fine of \$500.

2262. Adulteration of physiological salt solution. U. S. v. 37 Cartons * * *. (F. D. C. No. 24292. Sample No. 10301-K.)

LABEL FILED: January 6, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about October 28, 1947, by Brewer & Co., Inc., from Worcester, Mass.

PRODUCT: 37 cartons, each containing 5 20-cc. vials, of *physiological salt solution* at New York, N. Y.

LABEL, IN PART: "Physiological Salt Solution (Isotonic Solution of Sodium Chloride, U.S.P.) Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be a drug, "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard. The article was contaminated with undissolved material, whereas the Pharmacopoeia provides that injections must be substantially free from undissolved material.

DISPOSITION: January 20, 1948. Default decree of condemnation and destruction.

2263. Adulteration of epinephrine hydrochloride injection. U. S. v. 60 Vials * * *. (F. D. C. No. 23180. Sample No. 66326-H.)

LIBEL FILED: June 9, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 18, 1947, by Lederle Laboratories, Inc., from Pearl River, N. Y.

PRODUCT: 60 vials of *epinephrine hydrochloride injection* at Philadelphia, Pa.

LABEL, IN PART: "Epinephrine Hydrochloride Injection U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Epinephrine Hydrochloride Injection," a drug, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard, since it was contaminated with undissolved material.

DISPOSITION: July 23, 1947. Default decree of condemnation and destruction.

2264. Adulteration of Betathine-S (Super B Complex). U. S. v. 64 Vials * * *. (F. D. C. No. 23962. Sample No. 20814-K.)

LIBEL FILED: November 7, 1947, District of Kansas.

ALLEGED SHIPMENT: On or about October 19, 1947, by Burton-Lewis, Inc., from St. Joseph, Mo.

PRODUCT: 64 vials of *Betathine-S (Super B Complex)* at Topeka, Kans.

LABEL, IN PART: "15 cc. Vial Betathine-S (Super B Complex) * * * For intramuscular or intravenous use."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, since it was represented to be for intravenous use and contained undissolved material, whereas an article which is represented to be for intravenous use should be free from undissolved material.

DISPOSITION: January 14, 1948. Default decree of condemnation and destruction.

2265. Adulteration and misbranding of estrogenic hormone. U. S. v. Hormorgano Corporation and Herman Meyer. Pleas of guilty. Fines, \$200 against each defendant. (F. D. C. No. 17868. Sample No. 3823-H.)

INFORMATION FILED: March 17, 1947, Eastern District of New York, against the Hormorgano Corporation, Jamaica, N. Y., and Herman Meyer, president and secretary.

ALLEGED SHIPMENT: On or about January 31, 1945, from the State of New York into the State of Pennsylvania.

NATURE OF CHARGE: Adulteration, Section 501 (d), crystalline estradiol and crystalline estrone had been substituted in part for "Estrogenic Hormone Obtained from Pregnant Mares' Urine, Consisting Principally of Estrone and Estradiol," which the article purported and was represented to be.

Misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium, but was fabricated from two or more ingredients; and its label failed to bear the common or usual name of each active ingredient, in that the designation "Estrogenic Hormone," borne on the

label, is not the common or usual name of any particular active ingredient, but is a generic name for a class of substances.

DISPOSITION: May 8, 1947. Pleas of guilty having been entered, the court imposed a fine of \$200 against each defendant.

2266. Adulteration of Neo-Femme Tablets. U. S. v. Winning-Peplow Co. Plea of nolo contendere. Fine, \$150. (F. D. C. No. 15525. Sample No. 70585-F.)

INFORMATION FILED: August 10, 1945, Southern District of California, against the Winning-Peplow Co., a partnership, Glendale, Calif.; charging the defendant with the giving of a false guaranty in violation of Section 301 (h).

ALLEGED VIOLATION: On or about October 7, 1943, the defendant sold and delivered to Martin Laboratories, Los Angeles, Calif., a quantity of estrogenic tablets in response to an order from Martin Laboratories, specifying that the tablets should contain 600 International Units of estrone. The defendant also prepared and delivered to the consignee an invoice containing a guaranty that the tablets were not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

Between October 7, and November 13, 1943, Martin Laboratories repacked the tablets into boxes bearing the name *Neo-Femme Tablets* and shipped the tablets from the State of California into the State of Oregon. The tablets so guarantied and shipped were adulterated.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess, in that it was sold and delivered in response to an order for tablets containing 600 International Units of estrone per tablet, whereas the article contained less than 300 International Units of estrone per tablet.

DISPOSITION: A demurrer to the information was filed on behalf of the defendant on the ground (1) that the guaranty was not signed by the defendant and (2) that the guaranty on its face was not effective beyond the point of manufacture, since it contained language stating "that all potencies are accurate at time of manufacture." The demurrer was subsequently overruled. Thereafter, a plea of nolo contendere was entered on behalf of the defendant, and on December 14, 1945, the court imposed a fine of \$150.

2267. Adulteration of Aluthyn Tablets. U. S. v. Flint, Eaton & Co. Plea of nolo contendere. Fine, \$500. (F. D. C. No. 22093. Sample Nos. 20984-H, 49913-H.)

INFORMATION FILED: July 7, 1947, Southern District of Illinois, against Flint, Eaton & Co., a corporation, Decatur, Ill.

ALLEGED SHIPMENT: On or about December 17, 1945, and January 17, 1946, from the State of Illinois into the States of Kansas and Alabama.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, since it was represented to contain $\frac{1}{8}$ grain of phenobarbital in each tablet, whereas it contained more than that amount of phenobarbital.

DISPOSITION: August 6, 1947. A plea of nolo contendere having been entered, the court imposed a fine of \$500.

2268. Adulteration of Panodyne Compound Tablets and Zemadine. U. S. v. The William A. Webster Co. Plea of nolo contendere. Fine, \$1,500. (F. D. C. No. 21437. Sample Nos. 864-H, 24026-H, 24683-H.)

INFORMATION FILED: November 14, 1947, Western District of Tennessee, against the William A. Webster Co., a corporation, Memphis, Tenn.

ALLEGED SHIPMENT: On or about September 18 and 19 and October 1, 1945, from the State of Tennessee into the States of Georgia, Mississippi, and Alabama.

NATURE OF CHARGE: *Panodyne Compound Tablets*. Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, in that each tablet of the article was represented to contain one grain of acetphenetidin and one-fourth grain of caffeine, whereas each tablet of the article contained less than one grain of acetphenetidin and (portion of article) less than one-fourth grain of caffeine.

Zemadine. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, in that the article was represented to contain 20 percent of alcohol and each ounce was repre-

sented to contain 0.427 grain of mercuric chloride, whereas the article contained less than 20 percent of alcohol and each ounce contained less than 0.427 grain of mercuric chloride.

DISPOSITION: November 21, 1947. A plea of nolo contendere having been entered, the court imposed a fine of \$1,500.

2269. Adulteration of Vitaroid Tablets. U. S. v. The Warren-Teed Products Co.
Plea of guilty. Fine, \$300. (F. D. C. No. 20178. Sample No. 35913-H.)

INFORMATION FILED: February 26, 1947, Southern District of Ohio, against The Warren-Teed Products Co., a corporation, Columbus, Ohio.

ALLEGED SHIPMENT: On or about November 6, 1945, from the State of Ohio into the State of Missouri.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, since it was represented on its labeling to contain not less than 2,000 U. S. P. units of vitamin A, 15.0 milligrams of ascorbic acid, and 0.5 milligram of thiamine hydrochloride in each tablet, whereas each tablet of the article contained less than the declared amounts of vitamin A, ascorbic acid, and thiamine hydrochloride.

The information charged also that the defendant shipped in interstate commerce a misbranded food known as *Cal-Vitaron Tablets*, as reported in notices of judgment on foods.

DISPOSITION: April 7, 1947. A plea of guilty having been entered, the court imposed a fine of \$300 on the count charging adulteration of the *Vitaroid Tablets* and a fine of \$300 on the other count, charging adulteration of the *Cal-Vitaron Tablets*.

2270. Adulteration and misbranding of saccharin tablets. U. S. v. 8 Drums * * *. (F. D. C. No. 21597. Sample No. 94180-F.)

LIBEL FILED: October 31, 1946, Southern District of New York.

ALLEGED SHIPMENT: On or about April 18, 1946, by the Harco Pharmaceutical Corp., from Newark, N. J.

PRODUCT: 8 drums each containing 250,000 $\frac{1}{4}$ -grain *saccharin tablets* at New York, N. Y.

LABEL, IN PART: (Drums) "Hanco * * * Saccharin $\frac{1}{4}$ U. S. P. Grs. Tablets."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article was represented to be "Soluble Saccharin Tablets," the name of which is recognized in the United States Pharmacopoeia, and its strength differed from the standard set forth in that compendium. The article contained not more than 67 percent of the declared amount of sodium saccharin, whereas the Pharmacopoeia provides that soluble saccharin tablets contain not less than 95 percent of the labeled amount of sodium saccharin.

Misbranding, Section 502 (a), the label statements, "Saccharin $\frac{1}{4}$ U. S. P. Grs. Tablets Each Contains Soluble Saccharin U. S. P. $\frac{1}{4}$ gr.," were false and misleading. (The article contained an average of 0.16 grain of soluble saccharin per tablet.)

DISPOSITION: January 31, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2271. Adulteration and misbranding of Lactobacillus acidophilus. U. S. v. 18 Bottles * * * (and 1 other seizure action). (F. D. C. Nos. 22572, 22787. Sample Nos. 82317-H, 82351-H.)

LIBELS FILED: March 3 and April 4, 1947, Eastern District of Washington.

ALLEGED SHIPMENT: On or about January 25 and February 6, 1947, by Kovac Laboratories, Inc., from Los Angeles, Calif.

PRODUCT: 47 8-ounce bottles of *Lactobacillus acidophilus* at Yakima, Wash.

LABEL, IN PART: "Kovac Type Culture Lactobacillus Acidophilus."

NATURE OF CHARGE: Adulteration, Section 501 (d), a culture containing essentially *Streptococci* had been substituted in whole or in part for a culture of *Lactobacillus acidophilus*.

Misbranding, Section 502 (a), the label statement "Culture Lactobacillus Acidophilus A condensed culture" was false and misleading as applied to the

product, which contained relatively few *Bacillus acidophilus* organisms and large numbers of *Streptococci*.

DISPOSITION: April 2 and May 1, 1947. Default decrees of condemnation and destruction.

2272. Adulteration and misbranding of Trench Mouth Solution. U. S. v. 123 Bottles * * *. (F. D. C. No. 24325. Sample No. 18865-K.)

LIBLE FILED: February 4, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about November 13, 1947, by Thompson Laboratories, Inc., from Richmond, Ind.

PRODUCT: 123 12-ounce bottles of *Trench Mouth Solution* at Dayton, Ohio. Analysis disclosed that the product consisted of water, potassium arsenite, dipotassium arsenate, potassium iodide, and alcohol, colored red and flavored with oil of cloves. Each fluid ounce of the article contained not less than 0.27 grain of potassium arsenite and not less than 1.82 grains of potassium iodide.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., (label) "Each fluid ounce represents Potassium Arsenite $\frac{1}{5}$ gr. * * * Potassium Iodide $1\frac{1}{2}$ gr."

Misbranding, Section 502 (a), the following label statements were false and misleading: "Trench Mouth Solution * * * a supplementary aid in the treatment of Vincent's Infection (Trench Mouth) and is also recommended for use after tooth extraction * * * for treatment of mucous membranes of the mouth and throat." These statements represented and suggested that the article was effective in the treatment of trench mouth, of conditions following tooth extraction, and of conditions involving the mucous membranes of the mouth and throat, whereas the article was not effective for such purposes.

DISPOSITION: March 11, 1948. Default decree of condemnation and destruction.

2273. Adulteration and misbranding of Elastoplast Coverlets. U. S. v. 18 Boxes * * *. (F. D. C. No. 24419. Sample No. 26735-K.)

LIBLE FILED: On January 21, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about November 25, 1947, by Duke Laboratories, Inc., from Stamford, Conn.

PRODUCT: 18 boxes of *Elastoplast Coverlets* at St. Louis, Mo.

LABEL, IN PART: (Box) "No. 303 100 $1\frac{1}{4}$ inch Oval Elastoplast Coverlets Elastic Adhesive Coverings Unmedicated Not Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [Adhesive Absorbent Compress]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fall below the standard set forth in such compendium since it was not sterile.

Misbranding, Section 502 (g), the article was not packaged as prescribed in the United States Pharmacopoeia, since each adhesive absorbent gauze was not packaged individually in such manner that sterility was maintained until the individual package was opened, and one or more individual packages were not packed in a second protective container, as required by the Pharmacopoeia.

DISPOSITION: March 8, 1948. Default decree of condemnation and destruction.

2274. Adulteration and misbranding of Sanacal, Verma-Caps, Anti-Flatulence Tablets, San-Areck Capsules, and Equine Purgative Capsules, and misbranding of Breeder's Compound. U. S. v. Curts-Folse Laboratories, Lloyd M. Curts, and Charles D. Folse. Plea of guilty. Fine, \$1,100 against the defendants, jointly. (F. D. C. No. 17804. Sample Nos. 66674-F, 66676-F, 98816-F, 99049-F, 99051-F, 13005-H.)

INDICTMENT RETURNED: October 4, 1946, District of Kansas, against the Curts-Folse Laboratories, a partnership, Kansas City, Kans., and Lloyd M. Curts and Charles D. Folse, partners in the partnership.

ALLEGED SHIPMENT: Between the approximate dates of March 28 and December 26, 1944, from the State of Kansas into the States of Indiana, Missouri, and Illinois.

LABEL, IN PART: "Sanacal * * * Santonin $2\frac{1}{2}$ grs. Calomel $2\frac{1}{2}$ grs. Aloin 5 grs. * * * Distributed By Anchor Serum Co., Indianapolis, Ind.," "Farmers Friend Brand 1 Pint Breeder's Compound Contains Yohimbine 3 grs. Sod.

Glycerophos 8 grs. Iron Phosphate 5 grs. Saw Palmetto 15 grs. Alcohol 2.2% Elixir Base q. s. 1 oz. * * * Made for Naylor Serum Co., Kansas City, Mo., "Farmers Friend Brand 100 Verma-Caps" * * * Contain Nicotine Sulphate 1 gr. Copper Sulphate 17½ grs. * * * Made for Naylor Serum Co., Kansas City, Mo., "Anti-Flatulence Tablets Contain Salicylic Acid 20 grs. Camphor Gum 5 grs. Oleoresin Ginger ½ gr. Oleoresin Capsicum ½ gr. Magnestum Sulphate * * * Curts-Folse Laboratories," "Equine Purgative Capsules Contain Aloes 210 grs. Calomel 10 grs. Colocynth 2½ grs. Barium Chloride 45 grs. Nux Vomica 40 grs. (Strychnine 46 gr.) * * * Curts-Folse Laboratories," or "San-Areck Capsules Contain Arecoline (Enteric Coated) 1/10 gr. Santonin ¼ gr. Areca Nuts 1 gr. Soda Bicarb. q. s. * * * Curts-Folse Labs."

NATURE OF CHARGE: *Sanacal.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, since it contained in each capsule more santonin and calomel than it was represented to contain. Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article contained not more than 2½ grains of santonin and not more than 2½ grains of calomel in each capsule and that the article would be efficacious in the treatment of large roundworms in swine. The article contained more santonin and calomel than represented, and it would not be efficacious in the treatment of large roundworms in swine.

Breeder's Compound. Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article contained 8 grains of sodium glycerophosphate and 5 grains of iron phosphate in each ounce, whereas the article contained no sodium glycerophosphate and no iron phosphate; and the name of the article was false and misleading, since the product was recommended for administration to horses, cattle, sheep, and swine, and the name represented and suggested that the article would be efficacious in the treatment of breeding difficulties of these animals, whereas the article would not be efficacious for such purposes.

Verma-Caps. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, since it contained in each capsule more nicotine sulfate and copper sulfate than it was represented to contain. Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading, since they represented and suggested that the article contained in each capsule not more than 1 grain of nicotine sulfate and not more than 17½ grains of copper sulfate and that the article would be efficacious in the treatment of infestation of stomach worms of sheep and goats. The article contained more nicotine sulfate and copper sulfate than represented and would not be efficacious for the purpose represented.

Anti-Flatulence Tablets. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and represented to possess, since it contained more salicylic acid than represented. Misbranding, Section 502 (a), the label statement "Tablets Contain Salicylic Acid 20 grs." was false and misleading, in that the name of the article was false and misleading since the product was recommended for administration to horses and cattle, and the name represented and suggested that the article would be efficacious in the treatment of flatulence of horses and cattle. The article would not be efficacious for such purpose.

Equine Purgative Capsules. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, since it contained more calomel and barium chloride than represented. Misbranding, Section 502 (a), the label statements "Capsules Contain * * * Calomel 10 grs. * * * Barium Chloride 45 grs." were false and misleading.

San-Areck Capsules. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, since it contained less arecoline than represented. Misbranding, Section 502 (a), the label statement "Capsules Contain Arecoline (Enteric Coated) 1/10 gr." was false and misleading.

DISPOSITION: February 10, 1947. Pleas of guilty having been entered, the court imposed a fine of \$1,100 against the defendants, jointly.

2275. Adulteration and misbranding of Chexit. U. S. v. 11 Bottles * * * (and 2 other seizure actions). (F. D. C. Nos. 22692, 22693, 23457. Sample Nos. 67567-H, 67568-H, 86876-H.)

LIBELS FILED: March 12 and 13 and June 24, 1947, District of Kansas and Western District of Wisconsin.

ALLEGED SHIPMENT: On or about March 25 and April 2, 1946, and March 25, 1947, by the United Farmers Exchange, from Council Bluffs, Iowa.

PRODUCT: *Chexit*. 11 3-pound bottles at Baldwin City, Kans., 12 1-pound bottles at Humboldt, Kans., and 61 $\frac{1}{2}$ -pound jars and 59 1-pound jars at Madison, Wis. Analyses disclosed that the product consisted chiefly of calcium carbonate, powdered nux vomica, poke root, ginger, fenugreek, and potassium iodide. The amount of potassium iodide in the various lots of the product ranged from 0.17 to 0.27 percent.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, since it contained less than the label declaration of 0.40 percent potassium iodide.

Misbranding, Section 502 (a), the name *Chexit* and the following statements on the label were false and misleading: "Chexit * * * Demulcent Anti-Acid Mixture. Suggested as a demulcent anti-acid to the bowels and stomach. May be used when the need of a demulcent anti-acid is indicated. Tonic to the appetite * * * Potassium Iodide .40% * * * For Calves, Lambs, Colts and Kids—Give one (1) tablespoonful Chexit twice daily on their tongue, if suckling, give the dam two tablespoonsfuls twice per day over feed for 2 days. May be repeated. For Sows with Suckling Pigs—Give sow one (1) tablespoonful Chexit twice daily in slop or mix in milk or scatter over feed for 2 days. May be repeated. Milch Cows * * * For Steers in the Feed Lot * * *. These statements represented and suggested that the article when used as directed would be effective to check disease conditions of the bowels and stomach of animals and that it was a tonic to the appetite of animals. The article when used as directed would not be effective for such purposes. The representation on the label that the article contained 0.40 percent of potassium iodide was also false and misleading, since it contained a smaller amount.

DISPOSITION: July 24 and 29 and October 28, 1947. Default decrees of condemnation and destruction.

2276. Adulteration and misbranding of prophylactics. U. S. v. 43 $\frac{1}{2}$ Gross and 112 $\frac{1}{2}$ Gross of Prophylactics. Tried to the court. Decree of condemnation. Product ordered released under bond. (F. D. C. No. 16888. Sample Nos. 18372-H, 18373-H.)

LIBEL FILED: July 21, 1945, District of Minnesota.

ALLEGED SHIPMENT: On or about June 19, 1945, by the Killashun Sales Division, from Akron, Ohio.

PRODUCT: 43 $\frac{1}{2}$ gross and 112 $\frac{1}{2}$ gross of *prophylactics* at Minneapolis, Minn. Examination of 108 samples from each of the 2 lots showed that 7.4 percent and 11.1 percent, respectively, were defective in that they contained holes.

LABEL, IN PART: "Xcello's Prophylactics," or "Silver-Tex Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: Gellman Brothers, Minneapolis, Minn., appeared as claimant, and on November 27, 1945, the case came on for trial before the court. At the conclusion of the testimony, the case was taken under advisement by the court, and on February 11, 1946, after consideration of the briefs and arguments of counsel, the court handed down the following opinion:

GUNNAR H. NORDEBYE, *District Judge*: "The above cause came before this Court on libel proceedings pursuant to 21 U. S. C. A. § 334.

"Mr. Victor E. Anderson, United States Attorney, and Mr. Clifford F. Hansen, Assistant United States Attorney, of St. Paul, Minnesota, appeared in behalf of the United States of America; and Mr. Maurice Weinstein, of Milwaukee, Wisconsin, (Mr. Ralph Stacker, of St. Paul, Minnesota, of counsel) appeared in behalf of the claimant.

"A libel of information was filed against the goods described in the caption on the theory that they were adulterated within the meaning of 21 U. S. C. A. § 351 (c) and that they were misbranded within the meaning of 21 U. S. C. A. 352 (a). The goods were labeled 'Prophylactics' on the carton in which they were contained, and the Government contends that such labeling constitutes misbranding within the meaning of the Act. The articles consist of certain rubber devices sold ostensibly for the purpose of preventing transmission of venereal disease. The government witnesses testified that, of the Xcello brand, 180 were tested and 14 contained holes; that 223 of the Silver-Tex brand were tested and 16 contained holes. Medical witnesses testified that the defective devices would not serve as a means for the successful prevention of the transmission of venereal disease.

"Section 351 provides:

A drug or device shall be deemed to be adulterated—

(c) If * * * its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

"Section 352 provides:

A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

"The government inspection has established that the devices tested were defective in the number indicated, and there can be no serious doubt that the strength and quality of these particular defective articles fell below that which they purported or were represented to possess. Furthermore, it seems clear that, being labeled 'Prophylactics,' there was misbranding within the meaning of the statute. These defective devices are not efficacious in furnishing protection from diseases.

"The problem presented, however, pertains to the right of the Government to condemn the entire shipment. It appears that on or about June 19, 1945, about 43½ gross of the Xcello brand and 112½ gross of the Silver-Tex brand were shipped from the manufacturer in Akron, Ohio, to a concern in Minneapolis. It is from this shipment that the samples were taken and the tests made, as stated above. The Government took two samples—a pre-seizure and a post-seizure. While the method by which the first sample was taken is not entirely clear in the record, it does appear that, in taking the post-seizure samples, the Government took one dozen articles from each of the 36 gross cartons of Xcellos, and from the three gross so selected 72 samples were taken at random. Six, or about 8 per cent of the 72, were found to be defective. In the pre-seizure test of the Xcello brand, 108 were selected and 8 were found to be defective, or about 8 per cent. The post-seizure samples of the Silver-Tex brand were obtained by substantially the same method of selection by which the Xcello post-seizure samples were selected. In the post-seizure test of this brand, 120 samples were taken; four, or 3.33 per cent, were defective. In the pre-seizure test of this brand, 108 were tested and 12 were defective, or approximately 11.11 per cent. The average defects, therefore, of all the tests is approximately 7.37 per cent, but of the entire shipment seized, a fraction of one per cent is definitely shown to be defective, and claimant contends that the Government has failed to sustain the burden of proof which rests on it in these proceedings in its attempt to condemn the entire shipment. It should be pointed out that apparently the only practical tests which the government representatives are able to make with the facilities available to them results in the article's being rendered useless after the test has been made. Concededly, the burden of proof rests upon the Government. United States v. 5 One-Pint Bottles, et al. (D. C. N. Y., 1934) 9 F. Supp. 990; United States v. 11½ Dozen Packages, (D. C. N. Y., 1941) 40 F. Supp. 208. But it does not follow that each individual article in the shipment must be tested. Inspection and condemnation on the basis of samples tested is clearly contemplated by the Act. In fact, the Act speaks of samples and their availability for testing. 21 U. S. C. A. § 334 (c). And the cases seem to contemplate that testing of samples is sufficient if the samples are representative ones. Andersen & Co. v. United States, (9 C. C. A., 1922) 284 F. 542; United States v. 200 Cases, et al., (D. C. Tex., 1923) 289 F. 157. No serious question is raised in this proceeding as to the samples taken being representative. But claimant contends that the Court cannot order the condemnation of good articles, and concededly some of the remaining articles are in all probability free from defects. However, in urging this contention, claimant fails

to distinguish between condemnation and the confiscation or sale of goods. Condemnation only sustains the Government's position that the goods as they were composed in interstate shipment violate the provision and purpose of the Federal Food and Drug Act. After the decree, the claimant can separate the good from the defective if it posts a bond, and thereby will be able to retain the balance of the goods. 21 U. S. C. A. § 334 (d). The very fact that part of the section of the Food and Drug Act which governs condemnation and confiscation procedure contains a section which permits the separation of the acceptable from the defective goods after condemnation indicates an intent and recognition by Congress that some of the shipment may not violate the Act, but nevertheless would be subject to a decree of condemnation together with the defective merchandise. In view of the fact that the tests which the government representatives have applied render the articles useless, it is highly improbable that the statute intended that only the defective articles are to be condemned. The impracticability of such a libel action is obvious and the impracticability of such a construction also seems clear. In effect, it would prevent application of the Act to many situations to which Congress intended it to be applied. But it is urged that the number of defectives are so low in proportion to the total number of articles involved in this proceeding that a grave injustice would result to the claimant if the entire shipment is condemned. Again, it may be reiterated that condemnation is not necessarily confiscation, and that representative sampling is permitted by the Act. Moreover, the Court is not required or permitted to establish any formula as to what tolerance of defects should be allowed, if any, in every type of libel proceeding before it determines that the Government has sustained the burden of proof as to any particular shipment. Suffice it to say that, on the state of the facts herein, and assuming that the same ratio of defectives would be found in the entire shipment, it would follow that over 1,500 defective articles would be found in this shipment. Such a number, if sold on the market, would constitute a potential menace to public health, and, in view of the claimed purpose and object of the devices, that is, the prevention of disease, are sufficient to sustain the libel proceedings herein.

"The purpose of the Federal Food and Drug Act requires that the Act be interpreted liberally. 'One of the declared purposes of the Federal Food, Drug and Cosmetic Act is to prohibit the movement in interstate commerce of adulterated and misbranded foods, drugs, devices, and cosmetics. United States v. Dotterweich, 320 U. S. 277, 280, 64 S. Ct. 134; * * * United States v. 1,851 Cartons, etc., (10 C. C. A., 1945) 146 F. 2d 760. Thereby Congress hoped to 'prevent injury to the public health,' United States v. Research Laboratories, (9 C. C. A., 1942) 126 F. 2d 42, by prohibiting the 'sale of inferior for superior articles,' United States v. 200 Cases, etc., (D. C. Tex., 1923) 289 F. 157; and protecting the uninformed from buying an article which was different from what it purported to be. United States v. Lexington Mill & Elevator Co., 232 U. S. 399, 409, 34 S. Ct. 337, 58 L. Ed. 658, L. R. A. 1915B, 774; United States v. 5 One-Pint Bottles, etc., (D. C. N. Y. 1934) 9 F. Supp. 990. If claimant's contention were adopted here, this purpose could not be carried out, for the practical difficulties involved would permit defective articles to move in commerce and to be sold to uninformed persons without affording the protection represented.

"The Circuit Court of Appeals for the Ninth Circuit expressed its views upon a similar problem with reference to food as follows:

It is further agreed that the court should not destroy 1,600 cases of good salmon because 400 cases of the same lot are found to be adulterated. In answer to this we need only say that destruction does not follow condemnation as a matter of course. Section 10 of the Act provides for the restoration of the goods on payment of the costs and the giving of a sufficient bond to the effect that the articles will not be sold or otherwise disposed of contrary to the provision of the Act. Under this provision the defendant in error may, and will doubtless be permitted to, separate the good from the bad, and the burden of so doing should rest upon it, and not upon the government or the ultimate consumer. If it cannot do this, it is its own misfortune, and it must suffer the consequences. Andersen & Co. v. United States (9 C. C. A., 1922) 284 F. 542, 545.

"United States v. 200 Cases, etc., (D. C. Tex., 1923) 289 F. 157, seems contra to the Anderson case. But it proceeds upon the theory that the shipment cannot be condemned unless every article therein has been shown to be defective. For the reasons noted above in discussing claimant's contention to the same effect, this case seems unsound.

"The claimant herein seems especially concerned, however, because it contends that, upon reinspection pursuant to the bonding procedure provided for in 21 U. S. C. A. § 334 (d), the articles will be rendered useless, or at least their quality and strength impaired by the wear occasioned by any further testing. But the purposes of the Act cannot be relaxed merely because of difficulties which may be encountered upon reinspection. The claimant's own testimony shows that these articles are inspected at the factory before shipment, and it contends that such methods of testing are the most modern known in this particular trade. No good reason is suggested why the same articles cannot be again subjected to the testing to which they were subjected at the factory before they entered the channels of interstate commerce. In any event, these goods are sent into commerce labeled 'Prophylactics.' The Act seeks to prevent the sale of articles labeled as prophylactics when in fact they are not. The burden of separating the good from the bad under these circumstances should rest on the claimant. Certainly, if the manufacturer desires to continue the labeling and representations as to the quality and strength of its products, it will have to contend with whatever hardships or inconveniences the violation of the law may entail.

"It follows from the foregoing that the Government is entitled to findings of fact and conclusions of law in harmony with the foregoing, as prayed for in its libel of information, with the right of the claimant to proceed under Section 334 (d) in accordance with the provisions therein contained.

"An exception is allowed to the claimant."

On April 22, 1946, judgment of condemnation was entered and the product was ordered released under bond to the claimant for the purpose of separating the good portion of the product from the bad, under the supervision of the Federal Security Agency.

The claimant subsequently took an appeal in the case to the United States Circuit Court of Appeals for the 8th Circuit, and on March 4, 1947, the following opinion was handed down by that court, which affirmed the district court's decision :

WOODROUGH, *Circuit Judge*: "This appeal is to reverse a judgment of condemnation entered after trial by the court upon a libel of information by the United States against a shipment of rubber prophylactics transported in interstate commerce from Akron, Ohio, to Minneapolis, Minnesota, and there seized from appellants who are the owners. The articles are sold ostensibly for the purpose of preventing transmission of venereal disease and were labeled in part Xcellos' Prophylactics and in part Silver Tex Prophylactics, and the condemnation was ordered pursuant to the Federal Food, Drug and Cosmetic Act, Sec. 304, 21 U. S. C. A. 334, upon the findings and conclusions of the court that the articles were adulterated within the meaning of 21 U. S. C. A. Sec. 351 (c) and were misbranded within the meaning of 21 U. S. C. A. Sec. 352 (a).

"Before the information of libel was filed, agents of the government purchased some of the articles and subjected them to tests, and after such filing and the seizure of the articles the parties stipulated in writing that the owners 'cannot perfect the evidence required to proceed with said case until furnished with a sample of said seized property,' and that representatives of the parties 'on inspecting said seized property can best determine what sample is necessary to constitute a representative sample thereof' and 'that the court may make the attached order' to permit examination and taking of representative samples of the articles. The court acted in accordance with the stipulation and issued the order agreed upon by the parties. In consequence all of the seized articles were not subjected to testing, and the findings and conclusions of the court in respect to the charges of adulteration and misbranding were drawn from the testimony showing the nature, uses and purposes of the articles, the scale and processes of manufacture, the packing, labelling and shipment, and the results of the tests of the samples taken pursuant to the stipulation and order.

"It appears that the articles are produced in quantities of millions by the manufacturer who has large investment in plant, machinery, material and product, and as the case is said to present the first instance of reported decision in the federal courts upon the application of the Act in interstate shipments of rubber devices of the kind involved through condemnation proceedings, the

grounds relied on to avoid condemnation were fully developed and argued at the trial and on this appeal. The tests of the samples taken from the shipment showed that it included a substantial percentage of 'leakers' having holes in them not discernible to the naked eye but of such size as to permit the passage of disease germs to and fro, which germs in the test carried to that extent remained alive and propagated. But it was also shown that a much larger percentage of the shipment in which the defective devices were indistinguishably commingled were not 'leakers' and were, therefore, disease preventive and prophylactic to the extent limited by the uses for which they are adapted. The tests applied to the samples rendered them unfit for sale in ordinary course and in some instances caused them to burst.

"The judgment of condemnation preserves to the owners the right accorded by Sec. 334 (d) to repossess themselves of the shipment and separate the defective articles therefrom and upon bringing the shipment into compliance with the Act under designated supervision, to sell the same.

"The position taken by the owners is that the Act does not confer the power to order condemnation of the whole shipment of commingled sound and defective articles; that the designation of the articles as Prophylactic was not 'misbranding' even as to the 'leakers' shown to have holes in them, and that the articles with the holes in the rubber of which they are composed, were not adulterated.

"The trial court filed a written opinion with its findings and conclusions, and the same is reported in 65 F. Supp. 534. It presents the issues in the case and contains a fair statement of the evidence and the grounds of decision. It also reflects careful consideration of all matters of defense asserted for the owners and meets all substantial contentions for their position. We think it continues to meet such contentions, notwithstanding additional briefs and arguments submitted to and considered by us on this appeal. The additional contention that the samples were not representative of the shipment is not sustained. Our study of the record has satisfied us that the charges of the libel of information are supported by substantial evidence and that the provisions of the Act relied on authorized the court to enter the judgment of condemnation of the whole shipment subject to the conditions for repossession, separation and restoration of the shipment to compliance contained in the judgment. We think that the judgment in accordance with the opinion of the trial court (and with its separately filed findings and conclusions) was in all respects correct and proper, and although we recognize the importance of the case to the appellants and as a precedent, we think no good purpose would be served by making a re-statement of it from the record before us. We approve the statement of the case, the findings and conclusions, and the reasoning and decision as set forth in the opinion of the trial court, and find no error therein, and therefore affirm the judgment entered in accordance therewith. Affirmed."

2277. Adulteration and misbranding of prophylactics. U. S. v. 69 Gross * * *
(and 1 other seizure action). (F. D. C. Nos. 23870, 23871. Sample Nos. 12936-K, 12945-K.)

LIBELS FILED: October 27 and 28, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about July 30, 1947, under the name World Merchandise Exchange & Trading Co., Inc., and on or about September 9, 1947, under the name World Merchandise Exchange, from New York, N. Y.

PRODUCT: 111 gross of *prophylactics* at Philadelphia, Pa. Examination of samples showed that 3.5 percent in one of the shipments and 5 percent in the other shipment were defective in that they contained holes.

LABEL, IN PART: "Lloyd's Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: January 7, 1948. Default decrees of condemnation and destruction.

2278. Adulteration and misbranding of prophylactics. U. S. v. 85 Gross * * *.
 (F. D. C. No. 19357. Sample No. 58245-H.)

LIBEL FILED: On or about April 5, 1946, District of Montana.

ALLEGED SHIPMENT: On or about April 12 and June 11, 1943, by Hardy, Newman & Co., from Chicago, Ill.

PRODUCT: 85 gross of *prophylactics* at Great Falls, Mont. Examination of samples showed that 3.7 percent were defective in that they contained holes.

LABEL, IN PART: "Texide."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "For Prevention of Disease" was false and misleading as applied to an article which contained holes.

DISPOSITION: May 15, 1946. Default decree of condemnation and destruction.

2279. Adulteration and misbranding of prophylactics. U. S. v. 49 Gross * * *. (F. D. C. No. 21097. Sample No. 49695-H.)

LIBEL FILED: September 23, 1946, Western District of Texas.

ALLEGED SHIPMENT: On or about August 29, 1946, by the Dean Rubber Manufacturing Co., North Kansas City, Mo.

PRODUCT: 49 gross of *prophylactics* at San Antonio, Tex. Examination of samples showed that 3.7 percent were defective in that they contained holes.

LABEL, IN PART: "Economy Package No. 16 Reservoir Ends 1 Gross 12's Peacock."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Scientifically Tested. Guaranteed against deterioration for two years. For your protection" were false and misleading as applied to an article containing holes.

DISPOSITION: May 8, 1947. Default decree of forfeiture and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

2280. Misbranding of Sanford's Garlic with Parsley Tablets, Improved Formula Super Potency Calcium Pantothenate Pan-A-Plex Paramino Benzoic Acid and High B-Complex Tablets, Super Potency Aller-Cedic (Improved) Capsules, Super Potency Nura-Plex Special Formula No. 10 Capsules, Arthadex Capsules, Hebron Tablets, and Super Potency Ultra Hy "E" Capsules. U. S. v. The Vitamin Store of Iowa and Milton S. Frankle. Pleas of guilty. Total fines, \$250 and costs. (F. D. C. No. 21432. Sample Nos. 18275-H to 18280-H, incl., 18282-H, 18284-H.)

INFORMATION FILED: February 6, 1947, Southern District of Iowa, against the Vitamin Store of Iowa, a partnership, Des Moines, Iowa, and Milton S. Frankle, a partner.

ALLEGED SHIPMENT: Between the approximate dates of February 21, 1944, and August 21, 1945, from the States of Ohio, Minnesota, and Illinois, into the State of Iowa.

ALLEGED VIOLATION: Between the approximate dates of February 21, 1944, and September 19, 1945. The Vitamin Store of Iowa, and Milton S. Frankle, while holding the above-named drugs for sale after shipment in interstate commerce, caused to be prepared and printed a number of circulars entitled "Vitamin Deficiencies" and "Aller-Cedic" and caused one or both of the said circulars to accompany each of said drugs, which acts resulted in the misbranding of the drugs.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars "Vitamin Deficiencies" and "Aller-Cedic" were false and misleading. These statements represented and suggested:

That the *Sanford's Garlic with Parsley Tablets* would be efficacious in the treatment of high blood pressure;

That the *Improved Formula Super Potency Calcium Pantothenate Pan-A-Plex Paramino Benzoic Acid and High B-Complex Tablets* would be efficacious to improve the life and lustre of hair, to restore the hair color, to make finger-

*See also Nos. 2252, 2253, 2255, 2257, 2260, 2261, 2270-2272, 2276-2279.

nails stronger, to benefit the nervous and digestive systems, and to contribute to energy, vitality, and general good health;

That the *Super Potency Aller-Cedic (Improved) Capsules* would be efficacious in the treatment of hay fever, asthma, rose fever, food allergies, hives, and sinus and bronchial trouble;

That the *Super Potency Nura-Plex Special Formula No. 10 Capsules* would be efficacious in the treatment of arthritis pains, neuritis pains, rheumatic pains, constipation, fatigue, nervousness, backaches, bleeding gums, and sciatica;

That the *Arthadex Capsules* would be efficacious in the treatment of arthritis;

That the *Hebron Tablets* would be efficacious to supply new zest and vitality;

And that the *Super Potency Ultra Hy "E" Capsules* would be efficacious in the treatment of sore backs, aching limbs, muscle inflammation, and bursitis (primary fibrosis); that it would be a factor for healthy muscle; and that it would be of value to the reproductive processes.

The products would not be efficacious for the purposes represented and suggested.

DISPOSITION: April 28, 1947. A plea of guilty having been entered on behalf of the corporation and Milton S. Frankle on all 8 counts, each defendant was fined \$25 on counts 1 and 2 and \$12.50 on counts 3 to 8, inclusive, a total fine of \$250, plus costs.

2281. Misbranding of Sulgly-Minol. U. S. v. Walter W. Gramer. Plea of guilty. Defendant given deferred sentence and placed on probation for 30 days. (F. D. C. No. 21459. Sample Nos. 19338-H, 50750-H.)

INFORMATION FILED: March 6, 1947, District of Minnesota, against Walter W. Gramer, Minneapolis, Minn.

ALLEGED SHIPMENT: On or about January 19 and 24, 1946, from the State of Minnesota into the States of Iowa and Wisconsin.

PRODUCT: Analysis disclosed that the product consisted essentially of an alkaline solution of lime and sulfur, together with a small amount of glycerin.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Recommended as an aid for the relief of arthritic and rheumatic pains" was false and misleading, since the article would not be efficacious as an aid for the relief of arthritic and rheumatic pains.

DISPOSITION: November 3, 1947. A plea of guilty having been entered, the court disposed of the case by imposition of a deferred sentence and by placing the defendant on probation for 30 days.

2282. Misbranding of Sul-Ray Colloidal Sulphur Mineral Baths. U. S. v. 80 Packages * * * and a number of placards. (F. D. C. No. 16044. Sample No. 2859-H.)

LABEL FILED: On or about April 18, 1945, District of Columbia.

PRODUCT: *Sul-Ray Colloidal Sulphur Mineral Baths*. 80 packages of the product were offered for sale in the District of Columbia by the Vita Health Food Co., Washington, D. C., and a number of placards entitled "Relief from Body Aches and Pains" accompanied this product. Examination indicated that the product consisted essentially of sodium sulfate, carbonate, phosphate, borax, and sulfur.

LABEL, IN PART: "Sul-Ray Colloidal Sulphur Mineral Baths * * * Sante Chemical Co. N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the placards and in a leaflet entitled "Sul-Ray Colloidal Sulphur Mineral Baths" enclosed with the article were false and misleading, since they represented and suggested that the article would be effective in bringing the world's great mineral baths into one's home; that it would be effective to bring relaxation and relief from aches, pain, and itching; that it would be effective in the treatment of rheumatism, arthritis, neuritis, gout, lumbago, sciatica, and generalized skin conditions; that it would stimulate circulation; that it would refresh and revitalize and bathe away aches, pains, and fatigue; that it would aid in eliminating body odor; that it would, if used frequently and for long periods, remedy stubborn cases of long standing; that it would insure deep, refreshing sleep if used before retiring; that sulfur is a remedy for diseases generally; and that colloidal sulfur would penetrate the skin. The article would not fulfill the promises of benefit stated and implied by such statements.

DISPOSITION: The Sante Chemical Co., Inc., claimant, having agreed to the removal of the case to the Eastern District of New York, an order directing such removal was entered on August 3, 1945. The claimant subsequently consented to the entry of a decree, and on March 25, 1946, judgment of condemnation was entered in the Eastern District of New York. In accordance with that judgment, an order was entered in the District of Columbia, providing for the destruction of the product.

2283. Misbranding of Sul-Ray Colloidal Sulphur Mineral Baths. U. S. v. 38½ Dozen Packages * * *. (F. D. C. No. 16053. Sample No. 4062-H.)

LIBEL FILED: April 21, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about December 15, 1944, and January 6, 1945, by the Sante Chemical Co., Inc., from New York, N. Y.

PRODUCT: 38½ dozen packages of *Sul-Ray Colloidal Sulphur Mineral Baths* at Philadelphia, Pa. Examination showed that the product consisted essentially of sodium sulfate, carbonate, phosphate, borax, and sulfur.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a leaflet entitled "Sul-Ray Colloidal Sulphur Mineral Baths" enclosed with the article were false and misleading, since they represented and suggested that the article would be effective in bringing the world's great mineral baths into one's home; that if added to the bath it would bring relaxation and relief from pain to those afflicted with rheumatism, arthritis, neuritis, and lumbago; that it would bring relief from itching in certain types of generalized skin conditions; that it would stimulate the circulation and would refresh and vitalize; that it would bathe away aches, pains, and fatigue; that it would aid in eliminating body odor; that it would, if used frequently and for long periods, remedy stubborn cases of long standing; and that it would insure deep, refreshing sleep if used before retiring. The article would not be effective in the treatment of the conditions named, and it would not fulfill the promises of benefit stated and implied.

DISPOSITION: March 25, 1946. The Sante Chemical Co., Inc., claimant, having agreed to the removal of the case to the Eastern District of New York, an order directing its removal was entered on December 6, 1945. The claimant subsequently consented to the entry of a decree, and on March 25, 1946, judgment of condemnation was entered in the Eastern District of New York.

2284. Misbranding of Sul-Ray Colloidal Sulphur Mineral Baths. U. S. v. 12 Dozen Packages and 7 Dozen Packages * * * (and 2 other seizure actions). (F. D. C. Nos. 16336, 16371, 16701. Sample Nos. 4090-H, 4091-H, 14775-H, 16537-H.)

LIBELS FILED: On or about June 2 and 27 and July 26, 1945, Eastern District of Pennsylvania and Northern District of Illinois.

ALLEGED SHIPMENT: Between the approximate dates of April 4 and May 3, 1945, by National HealthAids, Inc., from New York, N. Y.

PRODUCT: *Sul-Ray Colloidal Sulphur Mineral Baths*. 19 dozen packages at Philadelphia, Pa.; and 429 packages and 5 cases, each case containing 6 packages, at Chicago, Ill. Examination indicated that the product consisted of baking soda, sodium sulfate, table salt, sulfur, cornstarch, a borate, and a phosphate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article was false and misleading in the same respect as that of the article reported in notices of judgment on drugs and devices, No. 2283.

Further misbranding, Section 502 (i), the containers in two of the lots were so filled as to be misleading, since they were too large to hold the quantity of the material placed therein.

DISPOSITION: The Sante Chemical Co., Inc., claimant for the Philadelphia lot and the Chicago lot of 429 packages, having agreed to the consolidation and the removal of the cases against both lots to the Eastern District of New York, and after the removal of the cases, having consented to the entry of a decree, judgment of condemnation was entered on March 25, 1946. No claimant having appeared for the Chicago lot of 5 cases, judgment of condemnation was entered against that lot and it was ordered destroyed.

2285. Misbranding of Morgan preparations. U. S. v. 300 Bottles of Morgan 1 Tablets, etc. (F. D. C. No. 17437. Sample No. 2928-H.)

LIBEL FILED: September 7, 1945, District of Columbia.

PRODUCT: 300 bottles of *Morgan 1* tablets, 300 bottles of *Morgan 2* tablets, 350 bottles of *Morgan 3* capsules, 300 bottles of *Morgan 4* tablets, 300 bottles of *Morgan 7* capsules, 325 bottles of *Morgan 9* tablets, and 350 bottles of *Morgan 14* capsules, at Washington, D. C., together with a number of accompanying booklets entitled "Class Lesson Number One," "Class Lesson Number Two," "Class Lesson Number Three," "Class Lesson Number Four," and "New Bodies for Old." The products were held and intended for sale in commerce within the District of Columbia.

LABEL, IN PART: "Morgan 1 7174M 50 Tablets Natural B-Complex-Aminos-Niacin Six S. C. Tablets contain: Vitamin B₁ * * * 1 milligram Vitamin B₂ * * * 2 milligrams Niacinamide * * * 30 milligrams Hydrolyzed Protein * * * 30 Grains"; "Morgan 2 7175M 50 Tablets Each S. C. tablet contains: (Balanced Multiple) Vitamin A * * * 5,000 U. S. P. Units Vitamin D * * * 1,000 U. S. P. Units Vitamin B₁ * * * 1.5 milligrams Vitamin B₂ * * * 3.0 Milligrams Vitamin C * * * 37.5 Milligrams Vitamin B₆ * * * 0.33 Milligrams Niacinamide * * * 30.0 Milligrams Calcium Pantothenate * * * 7.5 Milligrams Calcium * * * 115.0 Milligrams Phosphorus * * * 115.0 Milligrams Iron * * * 5.0 Milligrams Natural Tocopherols 3.0 Milligrams"; "Morgan 3 7176M 50 Capsules (Natural Mixed Tocopherols) Each capsule contains: 46 Milligrams natural mixed tocopherols, equivalent to 30 Milligrams of Alpha-Tocopherol"; "Morgan 4 7177M 100 Tablets (Bone Flour) Each 7½ Grain tablet contains: Purified, Medicinal Bone Flour prepared from selected bones of young Government inspected cattle"; "Morgan 7 7178M 50 Capsules (Lecithin-Vitamin D) Each capsule contains: 4 grains of pure Soybean Lecithin in 3 minims of Soybean oil with 150 U. S. P. Units or approx. ¼ of the minimum daily requirement of vitamin D"; "Morgan 9 7179M 100 Tablets Each S. C. tablet Contains: Dehydrated Pacific Kelp * * * 455 Milligrams (Equivalent to 7 Grains)"; "Morgan 14 7180M 50 Capsules (3 Minims Vitamin F) Free fatty acids of Linoleic and Linolenic Acid."

In addition, the label of each product bore the statement "Distributor Sarah I. Morgan, 1809½ Pa. Ave., Balt., Md."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklets were false and misleading, since they represented and suggested that the articles, singly or in combination, would be effective for supplying mineral and amino acid deficiencies in the diet; for helping the heart and memory retention; for bursitis, rheumatism, arthritis, muscular weakness, and sterility; for protecting vitamin A from undue oxidation; for preventing lawless cellular growth; for energizing the brain; for nervous breakdowns, exhaustion, irritability, and negativity; for producing hemoglobin regeneration and increasing red blood count; for nourishing glands, nerves, brain, and sex cells; for a defense against old age; for preventing wrinkles, kidney diseases, excessive dandruff, and skin diseases; for rejuvenation; for reducing; for catarrh and sinus disorders; for nourishing synovial membranes and keeping the blood in a fluidic state; for supplying substances needed by fingernails and teeth; for increasing the circulation of blood to the head and feeding the pituitary and pineal glands; for preventing thickening of tissues between the brain cells; for increasing the rate at which sensations, ideas, and nerve impulses travel; for giving stability to the body tissues and enabling them to carry oxygen; for remedying wrinkled and aged skin, psoriasis, kidney degeneration, nervous breakdown, sterility, abnormalities of the skin, and eczema; for underweight, inflammatory swelling, and deafness; for preventing degeneration of the eighth nerve and muscles of the ear; for preventing abnormal thickening of bone structure, decreased resistance to infections, anemia, altered state of water balance, retardation of healing of wounds, mental and physical inefficiency, and atrophy of the endocrine glands; for supplying material needed in cases of ulcers, kidney disorders, burns, surgery, pregnancy, and lactation; for maintaining the health of the pituitary gland; for preventing cataracts; for maintaining normal muscle health; for making hydrochloric acid in the stomach; for supplying a substitute for ordinary salt in high blood pressure; for feeding ulcer cases; for the formation of blood and hemoglobin; for elimi-

nating growths; for leucorrhea, ulcers, disturbances of the internal membranes, hay fever, and asthma; for the prevention of brain tumors, violent headaches, hallucinations, blindness, malformation and crowding of the teeth, protrusion of the upper jaw, recession of the lower jaw, underweight, overweight, failure of the sex glands to mature at puberty, gigantism, atrophy and degeneration of the sex glands, enlargement and degeneration of the pituitary gland, and pituitary strain; and for vitalizing the reproductive organs and glands. The article would not be effective for such purposes.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: Sarah I. Morgan, Baltimore, Md., appeared as claimant and filed an answer consenting to the destruction of the *Morgan 14* capsules. The claimant consented also to the condemnation of the other products, but prayed for their release under bond. On November 8, 1945, judgment of condemnation was entered and it was ordered that the *Morgan 14* capsules be destroyed and that the other products be released under bond for remanufacturing and relabeling under the supervision of the Food and Drug Administration. On June 14, 1946, and with the consent of the claimant, an amended decree was entered, ordering that all of the products, together with the accompanying booklets, be destroyed.

2286. Misbranding of Morgan preparations. U. S. v. 100 Bottles of Morgan 1 Tablets, etc. (F. D. C. No. 17461. Sample No. 10928-H.)

LIBEL FILED: September 12, 1945, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about August 31, 1945, Sarah I. Morgan caused the Q-V Corporation to ship quantities of the Morgan preparations from Kalamazoo, Mich., to Pittsburgh, Pa.; and on or about September 10, 1945, Sarah I. Morgan caused J. T. Regardie to ship a number of booklets relating to the preparations from Silver Spring, Md., to Pittsburgh, Pa.

PRODUCT: 100 bottles of *Morgan 1* tablets, 200 bottles of *Morgan 2* tablets, 200 bottles of *Morgan 3* capsules, 200 bottles of *Morgan 4* tablets, 100 bottles of *Morgan 7* capsules, and 100 bottles of *Morgan 9* tablets, at Pittsburgh, Pa., together with a number of accompanying booklets entitled "Class Lesson Number One," "Class Lesson Number Two," "Class Lesson Number Three," "Class Lesson Number Four," and "New Bodies for Old."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the products was false and misleading in the same respects as the labeling of the products involved in the preceding notice of judgment, No. 2285.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On September 26, 1945, Sarah I. Morgan, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the products were ordered released under bond for relabeling under the supervision of the Federal Security Agency. On May 27, 1946, pursuant to the consent of the claimant, an order was entered providing for the destruction of the products.

2287. Misbranding of thyroid extract. U. S. v. 2 Bottles * * *. (F. D. C. No. 23938. Sample No. 43553-H.)

LIBEL FILED: October 28, 1947, Southern District of California.

ALLEGED SHIPMENT: On or about July 30, 1947, by Wilson Laboratories, from Chicago, Ill.

PRODUCT: 2 bottles of *thyroid extract* at Glendale, Calif.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Each CC contains .043 percent Iodine Derived from Thyroid Glands. This amount is contained in 3 grains Thyroid U. S. P." was misleading, since it represented and suggested that each cubic centimeter of the article contained the physiologically active principles of 3 grains of thyroid, as defined and described in the United States Pharmacopoeia, whereas each cubic centimeter of the article exhibited less than half of the physiologic activity produced by 3 grains of U. S. P. thyroid.

DISPOSITION: November 25, 1947. Default decree of condemnation and destruction.

2288. Misbranding of Reiner's Rinol. U. S. v. 27 Bottles * * * and a quantity of printed matter. (F. D. C. No. 23633. Sample No. 83269-H.)

LIBEL FILED: August 14, 1947, Northern District of Indiana.

ALLEGED SHIPMENT: On or about March 20 and May 26, 1947, by the Reiner Medicine Co., from Cincinnati, Ohio.

PRODUCT: 27 8-ounce bottles of *Reiner's Rinol* at Marion, Ind., together with a number of circulars entitled "Reiner's Rinol" and one easel-type display headed "Rheumatism Take Reiner's Rinol." Examination showed that the product consisted essentially of sodium salicylate (12 percent), sodium citrate, potassium iodide, water, and alcohol.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars and on the easel-type display were false and misleading, since they represented and suggested that the article was an adequate treatment for rheumatism, arthritis, neuritis, and lumbago; that it would remove many poisons from the body and relieve congestion caused by poisons lodging in the joints; that it was a definite and effective treatment for arthritis and rheumatism; that it would eliminate poisons by its action on the urinary tract, liver, nerves, and blood; and that it would influence the cause of rheumatism and arthritis. The article was not an adequate treatment for the diseases mentioned, and it would not accomplish the benefits represented.

DISPOSITION: October 1, 1947. Default decree of condemnation and destruction.

2289. Misbranding of Pandermis No. 2. U. S. v. 104 Jars * * *. (F. D. C. No. 23651. Sample No. 99903-H.)

LIBEL FILED: On or about August 25, 1947, District of New Jersey.

ALLEGED SHIPMENT: On or about June 23, 1947, by Aubrey L. Marriner, of Boston, Mass.

PRODUCT: 104 jars of *Pandermis No. 2* at Camden, N. J. Examination showed that the product contained the ingredients stated on the label.

LABEL, IN PART: (Jar) "No. 2 Pandermis Formula Contains Oil of Cade, Beechwood, Creosote, Oil of Tar, Balsam of Peru, Boric Acid, Sodium Bicarbonate, Glycerine, and Petrolatum * * * Net Contents 1½ Ozs. Pandermis Co. Allston Station, Boston, Mass."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the jar label, display cards, and before-and-after photographs accompanied by legends, were false and misleading, since they represented and suggested that the article was effective in the treatment of pimples, blackheads, itch, scabies, ringworm, barber's itch, eczema, scalp or foot sores, and skin ailments in general. The article was not effective for such purposes.

DISPOSITION: November 28, 1947. Default decree of condemnation and destruction.

2290. Misbranding of Chlorogen devices. U. S. v. 4 * * *, etc. (and 1 other seizure action). (F. D. C. Nos. 23843, 24319. Sample Nos. 26001-K, 26342-K.)

LIBELS FILED: October 10, 1947, and January 26, 1948, Southern District of Illinois and Eastern District of Missouri.

ALLEGED SHIPMENT: On or about July 1 and 12 and December 3, 1947, by the Chlorogen Co., from Phoenix, Ariz.

PRODUCT: 5 *Chlorogen devices* at Decatur, Ill., and St. Louis, Mo., together with a number of leaflets entitled "Chlorogen Therapy" and a number of circulars entitled "Chlorogen Respiratory Therapy." Examination showed that the article was an electrical device for the production of chlorine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflets and circulars were false and misleading, since they represented and suggested that the device when used as directed was effective in the treatment of sinus infections, upper respiratory diseases, rheumatoid (infectious) arthritis, and internal diseases, secondary to toxicosis from nasal mucous and sinus infections. The device when used as directed was not effective in the treatment of such conditions.

DISPOSITION: November 19, 1947, and February 19, 1948. No claimant having appeared, judgments of condemnation were entered. It was ordered that the

devices be delivered to the Food and Drug Administration for testing and exhibit purposes and that the Food and Drug Administration destroy the devices when no longer needed for such purposes.

2291. Misbranding of Chlorogen devices. U. S. v. 2 * * *, etc. (F. D. C. No. 22688. Sample No. 75005-H.)

LIBEL FILED: March 12, 1947, Northern District of California.

ALLEGED SHIPMENT: On or about November 23, 1946, by the Chlorogen Co., from Phoenix, Ariz.

PRODUCT: 2 *Chlorogen* devices at San Francisco, Calif., together with 200 leaflets entitled "Chlorogen Therapy" and 2 sets of mimeographed sheets entitled "Chlorogen Chlorine Gas Generating Inhalator Operating Instructions." Examination showed that the article was an electrical device for the production of chlorine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflets and mimeographed sheets were false and misleading, since they represented and suggested that the device when used as directed was effective in the treatment of sinusitis, bronchial asthma, arthritis, bronchitis, common colds, glandular dysfunctions, sore throat, inflamed tonsils, migraine headaches, and goiter. The device when used as directed was not effective in the treatment of such conditions.

DISPOSITION: On April 9, 1947, the Chlorogen Co. appeared as claimant and filed an answer to the libel, denying that the device was misbranded. On September 17, 1947, an order was entered by the court, pursuant to which the devices were turned over to the Food and Drug Administration for the purpose of conducting experiments and tests. Thereafter, the claimant having admitted the allegations of the libel and consented to the entry of a decree, judgment of condemnation was entered on November 7, 1947. It was ordered that the United States marshal destroy the devices upon their receipt from the Food and Drug Administration, at the conclusion of the experiments and tests.

2292. Misbranding of Sun-Kraft Health Lamps. U. S. v. 20 * * *. (F. D. C. No. 24299. Sample No. 32209-K.)

LIBEL FILED: January 6, 1948, Northern District of California.

ALLEGED SHIPMENT: On or about November 20, 1946, by Sun Kraft, Inc., from Chicago, Ill.

PRODUCT: 20 *Sun-Kraft Health Lamps* at San Francisco, Calif. Examination showed that each lamp consisted of a cold quartz-type lamp mounted on a metallic base and equipped with a timing mechanism. This type of lamp emits ultraviolet radiations.

LABEL, IN PART: (Carton) "Sun-Kraft Mercury Quartz Ultraviolet Health Lamp"; (lamp) "Model A-1 * * * 112415" (or other serial number).

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the booklet entitled "How To Use Your Sun-Kraft," which was shipped with the lamps, were false and misleading, since the lamps were not capable of producing the following benefits stated and implied: "ultraviolet rays, * * * kill bacteria, * * * strengthen bones and teeth, and help the body to combat various ailments. * * * stimulate circulation * * * using Sun-Kraft for stubborn skin conditions * * * For Skin Conditions such as: Acne, Eczema, Psoriasis, Athlete's Foot * * * Daily irradiations may be advisable in cases of stubborn skin conditions, * * * For Respiratory Conditions such as: Asthma, Sinus, Bronchitis, Hay Fever, Catarrh and Colds * * * For Arthritis, Rheumatism, Neuritis, etc. * * * For Hair and Scalp * * * For respiratory conditions in children. * * * Another Important Use Of Sun-Kraft is Sterilization of Air. * * * The ultraviolet rays of Sun-Kraft and the activated ozone will sterilize your room, reducing the bacterial content of the air."

DISPOSITION: January 19, 1948. Hale Bros. Stores, Inc. of San Francisco, Calif., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the lamps were ordered released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE*

- 2293. Misbranding of Dr. Jespersen's Fowlton, Dr. Jespersen's Improved D. R. D., and Dr. Jespersen's Gets-em Poultry Flock Wormer.** U. S. v. Dr. Aage P. Jespersen (Dr. Jespersen's Laboratories). Plea of nolo contendere. Fine, \$600 and costs. (F. D. C. No. 21442. Sample Nos. 51042-H, 51051-H, 51052-H.)

INFORMATION FILED: May 13, 1947, Northern District of Iowa, against Dr. Aage P. Jespersen, trading as Dr. Jespersen's Laboratories, Spencer, Iowa.

ALLEGED SHIPMENT: On or about January 12 and 22, 1946, from the State of Iowa into the State of Minnesota. A number of booklets entitled "Some Poultry Diseases Their Symptoms and a Guide for Their Control" were shipped on or about September 24, 1945, to the consignee of the "Fowlton," and a number of the booklets were shipped with the other products.

PRODUCT: Analyses disclosed that the *Dr. Jespersen's Fowlton* consisted of approximately 98 percent water; very small proportions of iron sulfate, potassium dichromate, and manganese sulfate; and a trace of potassium iodide, colored with an orange dye; that the *Dr. Jespersen's Improved D. R. D.* consisted of approximately 97 percent water; very small proportions of manganese sulfate, the phenolsulfonates of calcium, sodium, and zinc; and approximately 4.3 grains of mercuric chloride per fluid ounce, colored with a green dye; and that the *Dr. Jespersen's Gets-em Poultry Flock Wormer* consisted of approximately 90 percent water, 13.95 grains of nicotine sulfate per fluid ounce, 0.96 grain of arecoline hydrobromide per fluid ounce, and small proportions of iron chloride, copper sulfate, and manganese sulfate, colored with a green dye.

NATURE OF CHARGE: *Dr. Jespersen's Fowlton*, misbranding, Section 502 (a), certain statements on the label and in the accompanying booklets were false and misleading. These statements represented and suggested that the article was a tonic for chickens, turkeys, and other poultry of any age; that it would be effective in the prevention and treatment of fowl cholera, fowl typhoid, and blackhead of poultry; that it would be effective in the treatment of sick flocks; that it would stop chickens from dying; that it would be effective in the prevention and treatment of coccidiosis; that it would induce faster growth and better health in poultry; that it would free the intestines of mucus and soothe the inflamed membranes; that it would be effective as a blood builder; that it would give birds more pep and vigor; that it would be effective in the treatment of severe cases of disease conditions of poultry; that it would keep poultry thrifty and productive; and that it would be effective as a disease fighter. The article would not be effective for such purposes.

Dr. Jespersen's Improved D. R. D., misbranding, Section 502 (a), certain statements on the label and in the booklets were false and misleading. These statements represented and suggested that the article would be efficacious as an intestinal astringent and in the prevention and treatment of roup, pox, and white diarrhea in poultry, and coccidiosis, colds, and other diseases of the respiratory tract of poultry, such as bronchitis, pneumonia, diphtheria, and laryngotracheitis. The article would not be efficacious for such purposes.

Dr. Jespersen's Gets-em Poultry Flock Wormer, misbranding, Section 502 (a), certain statements on the label and in the booklets were false and misleading. These statements represented and suggested that the article would be efficacious as a flock wormer in the removal of all types of intestinal worms and tape worms; that it would be efficacious to free birds from worms and make birds more thrifty; that it would cause greater profits to result from the use of the product; that it would enable birds to grow and gain faster and to go on the market earlier; and that it would be efficacious in the treatment of range paralysis. The article would not be efficacious for such purposes.

DISPOSITION: October 21, 1947. A plea of nolo contendere having been entered, the court imposed a fine of \$200 on each of the 3 counts of the information, plus costs.

- 2294. Misbranding of Gambine Injection Ointment.** U. S. v. 168 Tubes * * *. (F. D. C. No. 23894. Sample No. 29012-K.)

LABEL FILED: November 7, 1947, District of Colorado.

*See also Nos. 2259, 2274, 2275.

ALLEGED SHIPMENT: On or about August 14, 1947, by Atlas Laboratories, Inc., from Akron, Ohio.

PRODUCT: 168 tubes of *Gambine Injection Ointment* at Denver, Colo.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Use in teat canal in treatment of local inflammation * * * Germicidal - Fungicidal" were false and misleading, since the article would not be effective in the treatment of local inflammatory conditions of the teat canal, and it was not germicidal or fungicidal.

DISPOSITION: December 10, 1947. Default decree of condemnation and destruction.

2295. Misbranding of Stoctone, M & M Chicken Spray, and Sulfatone Number Two. U. S. v. 17 Bottles, etc. (F. D. C. No. 23181. Sample Nos. 68434-H to 68436-H, incl.)

LIBEL FILED: June 24, 1947, District of Nebraska.

ALLEGED SHIPMENT: On or about May 1, 1947, by the M & M Livestock Products Co., from Clarion, Iowa.

PRODUCT: 10 250-tablet bottles and 7 1,000-tablet bottles of *Stoctone*, 7 1-quart bottles of *M & M Chicken Spray*, and 47 3-pound bottles of *Sulfatone Number Two*, at Pilger, Nebr., together with a number of circulars, which were shipped with the product, entitled "Announcing—New Sulfatone and Stoctone for Livestock and Poultry." Analyses showed that the *Stoctone* consisted essentially of sodium arsanilate, ammonium phenolsulfonate, and boric acid; that the *M & M Chicken Spray* was essentially a petroleum distillate, such as kerosene; and that the *Sulfatone Number Two* consisted essentially of sulfanilamide, sulfathiazole, copper sulfate, potassium iodide, sulfaguanidine, and sulfate of iron with bicarbonate of soda, charcoal, linseed oil meal, and sodium chloride.

NATURE OF CHARGE: *Stoctone*. Misbranding, Section 502 (a), certain statements in the labeling were false and misleading. These statements represented and suggested that the article when used as directed would be effective in the treatment of blackhead and coccidiosis in turkeys and hemorrhagic septicemia (bloody scours) in hogs, whereas it would not be effective for such purposes.

M & M Chicken Spray. Misbranding, Section 502 (a), certain statements on the label were false and misleading. These statements represented and suggested that the article contained 100 percent active ingredients and that it would be effective in the treatment of colds, pneumonia, flu, and other respiratory ailments of poultry, whereas it did not contain 100 percent active ingredients and would not be effective for the purposes represented. Further misbranding, Section 502 (e) (1), the label failed to bear the common or usual name of the article; and, Section 502 (b) (2), it failed to bear an accurate statement of the quantity of the contents.

Sulfatone Number Two. Misbranding, Section 502 (a), certain statements in the labeling were false and misleading. These statements represented and suggested that the article would be effective in the treatment of necrotic enteritis, colds, influenza, and scours in hogs, and white diarrhea in small pigs; that it would be effective at breeding time in settling sows; that it would be effective as a treatment for brucellosis during the gestation period and at farrowing time; and that it would be effective to keep hogs healthy. The article would not be effective for such purposes.

DISPOSITION: August 15, 1947. Default decree of condemnation and destruction.

DRUG ACTIONABLE BECAUSE OF OMISSION OF, OR UNSATISFACTORY, INGREDIENTS STATEMENTS*

2296. Misbranding of Ramol. U. S. v. Benjamin Ostroff. Plea of nolo contendere. Fine, \$75 and costs. (F. D. C. No. 23234. Sample Nos. 52766-H, 53921-H, 53922-H, 60869-H.)

INFORMATION FILED: October 7, 1947, Western District of Pennsylvania, against Benjamin Ostroff, Pittsburgh, Pa.

ALLEGED SHIPMENT: On or about September 20 and October 1, 18, and 30, 1946, from the State of Pennsylvania into the State of Ohio.

* See also Nos. 2251, 2252, 2255, 2265; veterinary preparations, Nos. 2259, 2295.

LABEL, IN PART: "Ramol No. 350 U. S. P."

NATURE OF CHARGE: Misbranding, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, i. e., mineral oil.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: December 12, 1947. A plea of nolo contendere having been entered, the court imposed a fine of \$75, plus costs.

2297. Misbranding of Ramol. U. S. v. 1 Barrel * * * (and 5 other seizure actions). (F. D. C. Nos. 22354, 22355, 22382, 22429 to 22431, incl. Sample Nos. 50368-H, 53921-H, 53922-H, 53936-H, 53939-H, 53941-H.)

LIBELS FILED: January 2, 17, and 24, 1947, Northern District of Ohio and Southern District of Mississippi.

ALLEGED SHIPMENT: Between the approximate dates of September 18 and December 28, 1946, by Benjamin Ostroff, from Pittsburgh, Pa.

PRODUCT: 6 55-gallon barrels of *Ramol* at Cleveland, East Cleveland, Akron, Barberton, and Canton, Ohio, and Jackson, Miss.

LABEL, IN PART: "Ramol 350 Oil U.S.P."

NATURE OF CHARGE: Misbranding, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, i. e., mineral oil.

DISPOSITION: March 6, April 1, and May 14, 1947. Default decrees of condemnation and destruction.

2298. Misbranding of Ramol. U. S. v. 1 Drum * * * (and 1 other seizure action). (F. D. C. Nos. 21666, 22329. Sample Nos. 49351-H, 50099-H.)

LIBELS FILED: November 29, 1946, and January 4, 1947, Southern District of Mississippi.

ALLEGED SHIPMENT: On or about July 31 and August 20, 1946, by the Frank-Pew Oil Co., from Cleveland, Ohio.

PRODUCT: 1 drum containing about 50 gallons, and 1½ drums (55-gallon size) of *Ramol* at Gulfport and Biloxi, Miss., respectively.

LABEL, IN PART: "From B. Ostroff * * * Ramol No. 350 U.S.P."

NATURE OF CHARGE: Misbranding, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, i. e., mineral oil.

DISPOSITION: February 19 and 21, 1947. Default decrees of condemnation and destruction.

2299. Misbranding of Ramol. U. S. v. 5 Drums * * *. (F. D. C. No. 22221. Sample No. 54265-H.)

LIBEL FILED: January 30, 1947, Southern District of Florida.

ALLEGED SHIPMENT: On or about November 6, 1946, by the Atlas Storage & Transfer Co., from Pittsburgh, Pa.

PRODUCT: 5 55-gallon drums of *Ramol* at Miami, Fla.

LABEL, IN PART: "Ramol 350 U.S.P."

NATURE OF CHARGE: Misbranding, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, i. e., mineral oil.

DISPOSITION: December 19, 1947. Default decree of forfeiture. The product was ordered delivered to public institutions, for use as a drug for charitable purposes.

DRUG ACTIONABLE BECAUSE OF FAILURE TO BEAR AN ACCURATE STATEMENT OF THE QUANTITY OF THE CONTENTS*

2300. Adulteration of boric acid ointment. U. S. v. 15 Cases * * *. (F. D. C. No. 22401. Sample No. 62758-H.)

LIBEL FILED: January 21, 1947, Northern District of California.

*See also Nos. 2252, 2255; veterinary preparations, Nos. 2259, 2295.

ALLEGED SHIPMENT: On or about October 10, 1946, by the Harco Pharmaceutical Corp., from Newark, N. J.

PRODUCT: 15 cases, each containing 144 tubes, of *boric acid ointment* at San Francisco, Calif. Examination showed that the article was short-weight.

LABEL, IN PART: "Boric Acid Ointment 5% Half U.S.P. Strength For Burns * * * Net Weight $\frac{3}{4}$ Oz."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents.

DISPOSITION: March 10, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered released to the American Birobidjan Committee, San Francisco, Calif.

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Parenteral drugs-----	2260-2265
Phenobarbital tablets-----	2256
Prophylactics-----	¹³ 2276-2279
Ramol-----	2296-2299
Reiner's Rinol-----	2288
Rheumatism, remedy for-----	2288
Saccharin tablets-----	2270
Salt solution, physiological-----	2262
Sanacal-----	2274
San-Areck Capsules-----	2274
Sanford's Garlic with Parsley Tablets-----	2280
Seconal pulvules-----	2251
Sodium salicylate ampuls-----	2260
Stoctone-----	2295

¹² (2255) Contains opinion of Circuit Court of Appeals, affirming action of District Court in revoking probation of defendant.

¹³ (2276) Seizure contested. Contains opinion of District Court and Circuit Court of Appeals.

N. J. No.	N. J. No.
Sulfanilamide tablets and sulfanilamide and sodium bicarbonate tablets----- 2256	Tescum Powders----- 2257
Sulfathiazole tablets 2251, ¹⁴ 2254, 2256	Thyroid extract----- 2287
Sulfatone Number Two----- 2295	tablets----- 2251, 2256
Sulgly-Minol----- 2281	Trench Mouth Solution----- 2272
Sul-Ray Colloidal Sulphur Mineral Baths----- 2282-2284	Verma-Caps----- 2274
Sun-Kraft Health Lamps----- 2292	Veterinary preparations----- 2259, 2274, 2275, 2293-2295
Super Potency Aller-Cedic (Improved) Capsules, Super Potency Nura-Plex Special Formula No. 10 Capsules, and Super Potency Ultra Hy "E" Capsules ----- 2280	Vitamin preparations----- 2269, 2280, 2285, 2286
	Vitaroid Tablets----- 2269
	Water for injection----- 2261
	Zemadine ----- 2268

SHIPPIERS, MANUFACTURERS, AND DISTRIBUTORS

N. J. No.	N. J. No.
Abbott Laboratories: nembutal capsules----- 2251	Curts-Folse Laboratories: Sanacal, Verma-Caps, Anti-Flatulence Tablets, San-Areck Capsules, Equine Purgative Capsules, and Breeder's Compound----- 2274
sulfathiazole tablets----- 2254	
Allen Laboratories: phenobarbital tablets----- 2256	Dean Rubber Mfg. Co.: prophylactics ----- 2279
Anchor Serum Co.: Sanacal----- 2274	Duke Laboratories, Inc.: Elastoplast Coverlets----- 2273
Atlas Laboratories, Inc.: Gambine Injection Ointment----- 2294	Ellis Drug Store: sulfathiazole tablets, thyroid tablets, seconal pulvules, and nembutal capsules----- 2251
Atlas Storage & Transfer Co.: Ramol----- 2299	Estro Chemical Co. See Falk, M. G.
Bramley, E. B.: Tescum Powders----- 2257	Falk, M. G.: water for injection----- 2261
Brewer & Co., Inc.: physiological salt solution----- 2262	Fletcher, C. P.: sulfathiazole tablets, thyroid tablets, seconal pulvules, and nembutal capsules----- 2251
Brown, R. J.: Brown's Neuritis Capsules----- 2252	Flint, Eaton & Co.: Aluthyn Tablets----- 2267
Brown, Thomas A., Pharmacy. See Brown, R. J.	Folse, C. D.: Sanacal, Verma-Caps, Anti-Flatulence Tablets, San-Areck Capsules, Equine Purgative Capsules, and Breeder's Compound----- 2274
Burton-Lewis, Inc.: Betathine-S (Super B Complex)----- 2264	Frank-Pew Oil Co.: Ramol ----- 2298
Certified Drug & Chemical Co.: thyroid tablets, sulfathiazole tablets, phenobarbital tablets, sulfanilamide tablets, and sulfanilamide and sodium bicarbonate tablets----- 2256	Frankle, M. S.: Sanford's Garlic with Parsley Tablets, Improved Formula Super Potency Calcium Pan-
Chlorogen Co.: Chlorogen devices----- 2290, 2291	
Curt, L. M.: Sanacal, Verma-Caps, Anti-Flatulence Tablets, San-Areck Capsules, Equine Purgative Capsules, and Breeder's Compound----- 2274	

¹⁴ (2254) Prosecution contested. Contains opinion of the Supreme Court.

N. J. No.	N. J. No.
Frankle, M. S.—Continued. tothenate Pan-A-Plex Para-mino Benzoic Acid and High B-Complex Tablets, Super Potency Aller-Cedie (Improved) Capsules, Super Potency Nura-Plex Special Formula No. 10 Capsules, Arthadex Capsules, Hebron Tablets, and Super Potency Ultra Hy "E" Capsules-----	Manning Herb House. <i>See</i> Manning, D. R.
Gramer, W. W.: Sulgly-Minol-----	Marriner, A. L.: Pandermis No. 2----- 2289
Harcos Pharmaceutical Corp.: boric acid ointment-----	Martin Laboratories: Neo-Femme Tablets----- 2266
saccharin tablets-----	Meyer, Herman: estrogenic hormone----- 2265
Hardy, Newman & Co.: prophylactics-----	Miller Electro Research Laboratories: Anatatherm (device)----- 2253
Hormergano Corp.: estrogenic hormone-----	Mills Sales Co. of New York, Inc.: phenobarbital tablets, thyroid tablets, sulfathiazole tablets, sulfanilamide tablets, and sulfanilamide and sodium bi-carbonate tablets----- 2256
Intra Products Co.: sodium salicylate ampuls-----	Morgan, S. I.: Morgan 1 tablets, Morgan 2 tablets, Morgan 3 capsules, Morgan 4 tablets, Morgan 7 capsules, and Morgan 9 tabs- lets----- 2285, 2286
Jacoby, David: phenobarbital tablets, thyroid tablets, sulfathiazole tablets, sulfanilamide tablets, and sulfanilamide and sodium bicarbonate tablets-----	Morgan 14 capsules----- 2285
Jespersen, Dr. A. P.: Dr. Jespersen's Fowlton, Dr. Jespersen's Improved D. R. D., and Dr. Jespersen's Gets- em Poultry Flock Wormer---	Murdock, C. B.: sodium salicylate ampuls----- 2260
Jespersen's, Dr., Laboratories. <i>See</i> Jespersen, Dr. A. P.	National HealthAids, Inc.: Sul-Ray Colloidal Sulphur Mineral Baths----- 2284
Killashun Sales Division: prophylactics -----	Naylor Serum Co.: Breeder's Compound and Verma-Caps ----- 2274
Kovac Laboratories, Inc.: Lactobacillus acidophilus-----	Ostroff, Benjamin: Ramol----- 2296-2298
Lederle Laboratories, Inc.: epinephrine hydrochloride in- jection-----	Pandermis Co.: Pandermis No. 2----- 2289
Lilly, Eli, & Co.: sulfathiazole tablets and sec- onal pulvules-----	Powell, S. A.: sodium salicylate ampuls----- 2260
M & M Livestock Products Co.: Stoctone, M & M Chicken Spray, and Sulfatone Number Two-----	Q-V Corp.: Morgan 1 tablets, Morgan 2 tab- lets, Morgan 3 capsules, Mor- gan 4 tablets, Morgan 7 cap- sules, and Morgan 9 tablets----- 2286
Manning, D. R.: Manning's Whoa Liniment, Bi- Lax Capsules, Manning's Fumigating Powder, Manix, Formula for Catarrh of the Bladder, Formula for Relief of High Blood Pressure, Formula for Relief of Coughs, and Formula for Asthma----- ¹² 2255	Random Veterinary Products, Inc.: 1 Shot A-Ran Treatment----- 2259
	Regardie, J. T.: Morgan 1 tablets, Morgan 2 tab- lets, Morgan 3 capsules, Mor- gan 4 tablets, Morgan 7 cap- sules, and Morgan 9 tablets----- 2286
	Reiner Medicine Co.: Reiner's Rinol----- 2288
	Sante Chemical Co., Inc.: Sul-Ray Colloidal Sulphur Mineral Baths----- 2282, 2283
	Sullivan, J. J.: sulfathiazole tablets----- ¹⁴ 2254

¹² (2255) Contains opinion of Circuit Court of Appeals, affirming action of District Court in revoking probation of defendant.

¹³ (2276) Seizure contested. Contains opinion of District Court and Circuit Court of Appeals.

¹⁴ (2254) Prosecution contested. Contains opinion of the Supreme Court.

N. J. No.	N. J. No.
Sullivan's Pharmacy. <i>See</i> Sullivan, J. J.	Vitamin Store of Iowa—Cont.
Sun Kraft, Inc.:	Potency Aller-Cedic (Improved) Capsules, Super Potency Nura-Plex Special Formula No. 10 Capsules, Arthadex Capsules, Hebron Tablets, and Super Potency Ultra Hy "E" Capsules----- 2280
Sun-Kraft Health Lamps----- 2292	
Supreme Pharmaceutical Co.:	Warren-Teed Products Co.:
Forfem Perles----- 2258	Vitaroid Tablets----- 2269
thyroid tablets----- 2251	Webster, William A., Co.:
Tescum Co. <i>See</i> Bramley, E. B.	Panodyne Compound Tablets and Zemadine----- 2268
Thompson Laboratories, Inc.:	Wilson Laboratories:
Trench Mouth Solution----- 2272	thyroid extract----- 2287
United Farmers Exchange:	Winning-Peplow Co.:
Cheexit-----	Neo-Femme Tablets----- 2266
Vita Health Food Co.:	World Merchandise Exchange:
Sul-Ray Colloidal Sulphur Mineral Baths----- 2282	prophylactics----- 2277
Vitamin Store of Iowa:	World Merchandise Exchange & Trading Co., Inc.:
Sanford's Garlic with Parsley Tablets, Improved Formula Super Potency Calcium Panthenate Pan-A-Plex Para-mino Benzoic Acid and High B-Complex Tablets, Super	prophylactics----- 2277

